

**CORRECTED
NON-CONFIDENTIAL
04-1323, -1487**

**United States Court of Appeals
For the Federal Circuit**

ARTHROCARE CORPORATION,

*Plaintiff/Counterclaim Defendant-
Appellee,*

and

ETHICON, INC.,

Counterclaim Defendant-Appellee,

v.

SMITH & NEPHEW, INC.,

*Defendant/Counterclaimant-
Appellant.*

**APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF DELAWARE IN 01-CV-504,
CHIEF JUDGE SUE L. ROBINSON**

**BRIEF FOR DEFENDANT/COUNTERCLAIMANT-APPELLANT
SMITH & NEPHEW, INC.**

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CERTIFICATE OF INTEREST

Counsel for the Defendant/Counterclaimant-Appellant Smith & Nephew, Inc.,
certify the following:

1. The full name of every party represented by us is:

Smith & Nephew, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by us is:

See above

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by us are:

Smith & Nephew Holdings, Inc.
Smith & Nephew (Overseas) Limited
TP Limited
Smith & Nephew plc

4. The names of all law firms and the partners or associates that appeared for the party now represented by us in the trial court or are expected to appear in this court are:

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MATERIAL OMITTED FROM NON-CONFIDENTIAL BRIEF

The material omitted from the Non-Confidential Brief relates to confidential agreements executed by Arthrocare Corporation, documents filed under seal with the district court, and Smith & Nephew, Inc.'s counterclaim, the dissemination of which the district court has restricted.

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STATEMENT OF RELATED CASES

Pursuant to Federal Rule of Appellate Procedure 47.5, counsel for Defendant/Counterclaimant-Appellant (“Smith & Nephew”) states that no appeal other than this consolidated action has been filed in this Court from the same district court proceedings. On April 29, 2004, Smith & Nephew filed in this Court a motion to stay the injunction issued by the district court. This Court denied the motion on June 3, 2004.

No other case is known to counsel to be pending in this or any other Court that will directly affect or be directly affected by this Court’s decision in the present pending appeal.

STATEMENT OF JURISDICTION

The district court had jurisdiction in this case under 28 U.S.C. §§ 1331 and 1338(a). This Court has exclusive jurisdiction over this appeal under 28 U.S.C. §§ 1292(a)(1), 1292(c)(1), and 1295(a)(1). Smith & Nephew's notice of appeal was filed timely under 28 U.S.C. § 2107(a) and Fed. R. App. P. 4(a)(1).

STATEMENT OF THE ISSUES

1. Did the district court err in denying Smith & Nephew's motion for judgment as a matter of law that the '536 patent is anticipated by the Roos article and the Roos patent, each of which clearly and convincingly discloses all of the claim limitations, including the "connector" and "electrically conducting fluid" limitations?

2. Did the district court err in dismissing Smith & Nephew's antitrust counterclaim, which alleges that ArthroCare Corporation ("ArthroCare") and its competitor Ethicon, Inc. ("Ethicon") entered into an agreement to restrain trade by {

}, without allowing Smith & Nephew to respond to the motion to dismiss?

3. Did the district court err in denying Smith & Nephew's motion for judgment as a matter of law relating to the '592 patent when the evidence was undisputed that the return electrodes of the accused products contact tissue during the claimed method and the jury failed to apply the court's claim construction?

4. Did the district court err in denying Smith & Nephew's motion for judgment as a matter of law that the '882 patent's Certificate of Correction is invalid when the intrinsic evidence is ambiguous as to the appropriate correction to claim 1?

STATEMENT OF THE CASE

ArthroCare sued Smith & Nephew on July 25, 2001, alleging infringement of U.S. Patents 5,697,536 (the “536 patent”), 5,697,882 (the “882 patent”), and 6,224,592 (the “592 patent”). [A281-86] Smith & Nephew denied infringement and included counterclaims for antitrust violations by ArthroCare.¹ [A302-13] The district court bifurcated the case into two stages: one for the patent issues, and one for the damages, willfulness, and antitrust issues. [A3336] The court stayed discovery and trial on the damages, willfulness, and antitrust issues until after the patent trial. [A3336]

The court issued its Markman order on April 9, 2003, and held the patent trial in May 2003. [A16-20] After the close of ArthroCare’s case-in-chief, Smith & Nephew moved for judgment as a matter of law based on a lack of infringement evidence. [A14940-72] Smith & Nephew twice more moved for judgment as a matter of law: once at the close of all evidence, [A73 (citing A15585 (1549:2-5))], and again prior to the jury charge, [A73 (citing A15647 (1700:16-23))]. The court reserved judgment on the motions, and sent the issues to the jury. [A15585-86 (1549:2-5 & 1553:7-9); A15441 (1161:22-1162:2); A15647 (1700:16-23); A73-74] The jury returned a verdict for ArthroCare. [A369-78]

¹ Smith & Nephew also named Ethicon as a defendant to the antitrust counterclaim. [A302-13]

Soon after the patent trial, on May 27, 2003, ArthroCare moved to dismiss Smith & Nephew's antitrust counterclaim. [A15912-13] Before Smith & Nephew's opposing brief was due, the court stayed all proceedings on the antitrust counterclaim "until further Order of the Court." [A16755 (12:21-24)] Ten months later, without ever lifting the stay, the court dismissed Smith & Nephew's antitrust counterclaim. [A26 n.1, 32] Smith & Nephew immediately requested reconsideration, [A18275-83], and filed an unopposed motion to lift the stay to permit it to file an opposition brief, [A18537-44]. The court declined to reconsider its ruling or lift the stay. [A127; A126; A135]

The court entered judgment for ArthroCare on the jury verdict on June 20, 2003. [A21-22] Smith & Nephew timely renewed its motion for judgment as a matter of law, [A17104-07; A17108-211], and filed a motion for a new trial, [A16765-72; A16773-816]. ArthroCare moved for a permanent injunction. [A15670-78] On March 10, 2004, the court denied both of Smith & Nephew's motions, and granted ArthroCare's motion for a permanent injunction. [A124-25; A33-123]

Smith & Nephew moved to stay the injunction pending appeal, [A18165-69], and for reconsideration of the rulings leading to the injunction, [A18275-83]. On April 27, 2004, the court issued an opinion declining to reconsider its earlier orders and stay the injunction. [A129-44; A146 (order)] The court then entered an

injunction permanently enjoining Smith & Nephew. [A155-163; A147-54 (original injunction)] This appeal followed.

STATEMENT OF THE FACTS

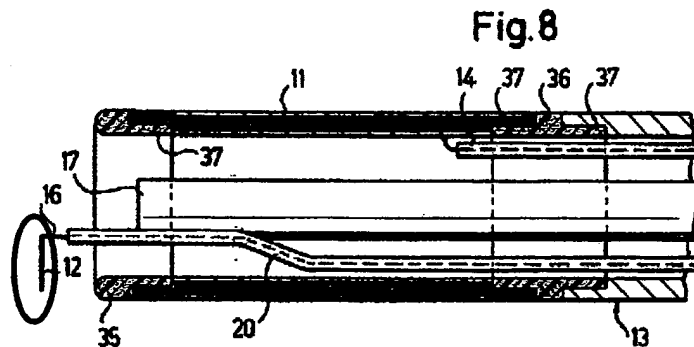
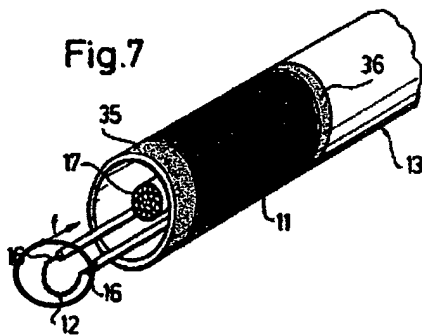
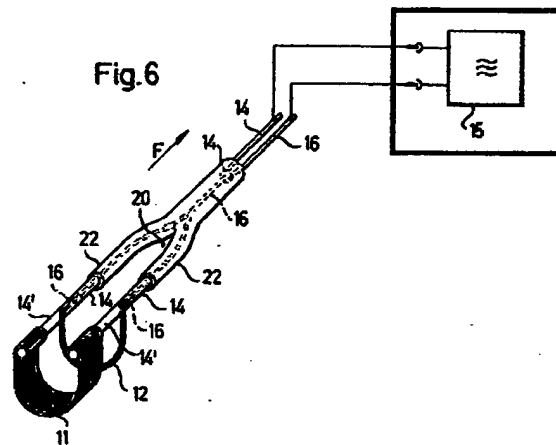
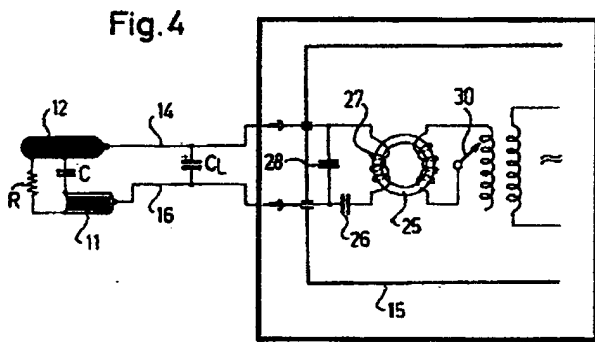
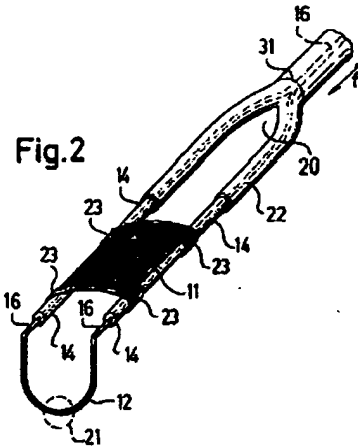
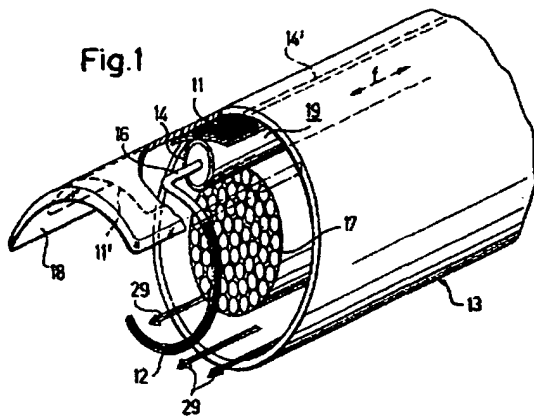
I. Electrosurgery Background

The patents-in-suit relate to electrosurgery, which involves the use of high frequency or radio frequency (RF) alternating current to ablate, cut, and/or coagulate tissue. [A36] Current flowing between one or more active and return electrodes located on an electrosurgical device causes these tissue effects. [A36] Doctors use electrosurgical devices in various surgeries, including minimally invasive arthroscopic surgeries that use a tiny camera to view a patient's joint, such as a knee or shoulder. [A4133-34]







II. The Prior Art – Electrosurgical Devices That Use Electrically Conductive Fluid to Complete the Circuit Between the Active and Return Electrodes

A. The Roos Patent

U.S. Patent No. 4,116,198 (the “Roos patent”) relates to an electrosurgical device for ablating and coagulating tissue within a patient's body. [A18671-80] Before the Roos invention, current often flowed from the active electrode back to the metal shaft and the optics of the device, thereby electrically charging these components. [A18676 (1:5-2:36)] This electrical charge frequently resulted in undesirable burns to tissue touching the shaft or the optics. [A18676 (1:62-2:4)]



Legend

 Return Electrode 11	 Active Electrode 12	 Leads 14, 16
 Washing Water 29	 High Frequency Generator 15	 Insulating Rings 35, 36

Roos discovered that adding a "neutral" return electrode close to the active electrode confined the current flow to the area between the two electrodes, preventing unwanted burns. [A18676 (2:18-36)] In addition, the Roos invention uses electrically conductive fluid to complete a defined conduction path between the active and return electrodes, in the vicinity of the tissue being treated, which reduces the risk of unwanted electrical stimulation. [See A18677 (4:51-57); A18679 (7:59-62)]

Specifically, the Roos invention includes an active "treatment" electrode 12 and a "neutral" return electrode 11 located near the distal end of the device (see figures on facing page). [A18676-78 (2:22-34 & 4:66-5:5); A18678-79 (6:61-7:1); A18672-75] The active electrode 12 is formed as a cutting loop located at the device tip. [A18677-78 (4:66-5:2); A18672-75] The neutral (return) electrode 11 may be located above (Fig. 2) or in front of (Fig. 6) the active electrode, or it may wrap completely around the shaft near its distal end (Figs. 7-8). [A18672-75; A15513 (1349:14-16)] The active and return electrodes 12, 11 are connected to opposite poles of a high frequency generator 15 through electrical leads 16, 14 that run toward the rear of the shaft. [A18678-79 (5:3-10, 5:30-37, & 6:67-7:7 (Two leads combine to form a single cable "leading to the rear end of endoscope 13.")); A18673 (Fig. 4)] Current flows from the active electrode 12 to the return electrode 11 through electrically conducting "washing liquid" 29 and through any tissue that

High
Frequency
Generator

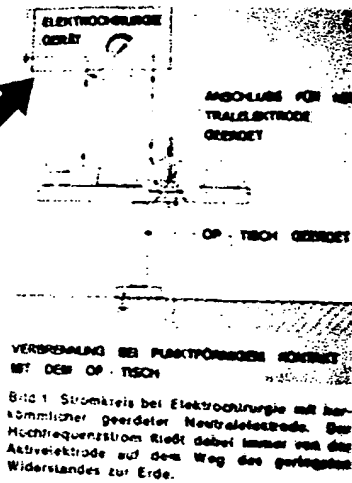


Figure 1: Electrosurgical circuit with conventional grounded neutral electrode. The high-frequency current in this case always flows from the active electrode to ground via the path of least resistance. [A18725]

Return
Electrode

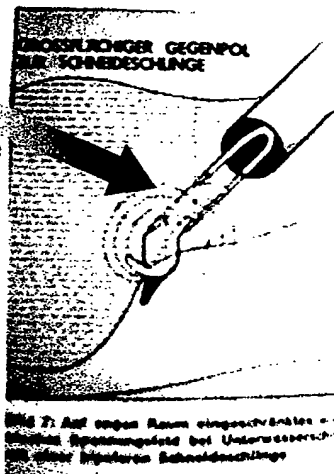


Figure 7: Electrical voltage field limited to a restricted area, during cutting with a bipolar cutting loop under water. [A18728]

Bild 6: Bipolare Elektroden-Anordnung zu Schneiden bei transurethraler Resektion: Der Strom fließt von der Schneideschlinge direkt zu der nahen schiffsförmigen Neutral-Elektrode

ISOLATION

GROSSFLÄCHIGER
GEGENPOL ZUR
SCHNEIDESCHLINGE
NEUTRALELEKTRODE

ISOLATION

FUNKTIONSPRINZIP

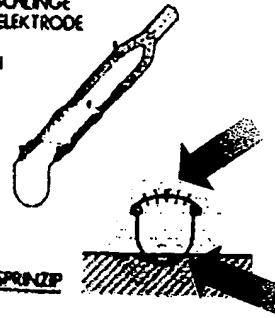


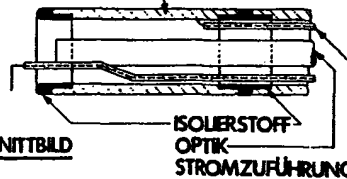
Figure 6: Bipolar electrode arrangement for cutting in the case of transurethral resections: The current flows from the cutting loop directly to the nearby lamelliform neutral electrode. [A18728]

Return
Electrode

Cutting
Loop



METAL RING AS
LARGE-AREA
ANTIPOLE TO THE
CUTTING LOOP
(NEUTRAL
ELECTRODE) [A18729]



SCHNITTBILD

ISOLIERSTOFF
OPTIK
STROMZUFÜHRUNG

SECTIONAL VIEW

INSULATING MATERIAL
OPTICAL SYSTEM
POWER SUPPLY
[A18729]

Bild 8: Bipolare Elektrodenanordnung zur transurethralen Resektion: Die Neutral-Elektrode ist als Metallring am Ende des Resektoskopschaftes angebracht.

Figure 8: Arrangement of bipolar electrodes for transurethral resection. The neutral electrode is attached as a metal ring at the end. [A18729]



Connector

Bild 9: Photographie des Instrumentes aus Abbildung 8: Die Neutral-Elektrode sitzt als Metallring am Ende des Resektoskopschaftes.

Figure 9: Photograph of the instrument from Figure 8. The neutral electrode is positioned as a metal ring at the end of the resectoscope. [A18729]

might contact the electrodes. [A18677 (4:51-57); A18679 (7:59-62); A18672 (Figs. 1-2); A18674-75 (Figs. 5-6 & 7-8)]

B. The Roos Article

The Roos invention also appears in a German article published in 1976. [A18719-24; A18725-34 (translation)] The article discloses several embodiments shown in the Roos patent. [Compare A18723 (Fig. 8) with A18675 (Figs. 7 & 8); compare also A18722 (Fig. 6) with A18672 (Fig. 2)]

Like the Roos patent, the Roos article discloses using electrically conductive fluid to carry current between the active and return electrodes. [A18728 (“The current flows directly from the cutting loop to the neutral electrode through the adjacent tissue to be cut and the irrigation liquid.”); see also A18731] This “new current pathway,” [A18729], prevents current from flowing to the shaft, thereby eliminating unintended burns. [A18726-27; A18722 (Fig. 5)] Figures 6 and 7 of the article (see facing page) show current flow lines for the “bipolar cutting loop.” [A18722] As shown, the current flows from the active cutting loop to a return electrode located on top of the device through electrically conducting “water.” [A18722; A18728 (Fig. 7 caption)]

Figures 8 and 9 of the article (see facing page) depict an alternative embodiment, similar to Figures 7 and 8 of the Roos patent, in which the return electrode wraps completely around the shaft of the device near its distal end.

[A18723] As seen in Figure 8 of the article, insulating material circumscribes the return electrode, which is spaced from the active electrode cutting loop to minimize contact with the target tissue during electrosurgical procedures. [A18723 (Fig. 8, showing “ISOLIERSTOFF” arrows); A18729 (Figure 8 caption)] Figure 8 further shows electrical wires running from the active cutting loop and the return electrode toward the rear of the device for connection to a high frequency power generator. [A18723; see also A18728 (Both electrodes are connected to “a high-frequency generator.”)] Figure 9 shows a connector at the proximal end that connects the device to the high frequency generator located outside the patient’s body. [A18723; see also A18720 (Fig. 1 showing the generator located above the patient)]

Thus, long before the alleged invention of the patents-in-suit, the prior art disclosed (1) using electrically conductive fluid to carry current between the active and return electrodes, (2) circumscribing the return electrode, which is spaced from the active electrode to minimize direct contact between the return electrode and target tissue, with an insulating member, and (3) coupling the active and return electrodes to a power source with a connector located near the proximal end of the probe.

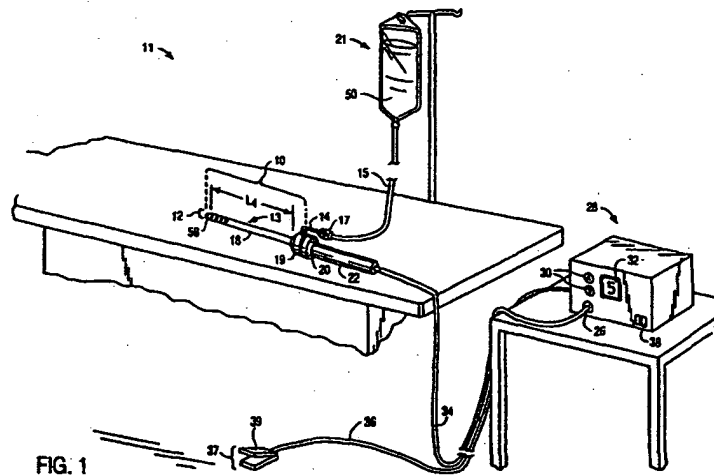
III. The Patents-in-Suit

The three asserted patents pertain to electrosurgical systems and methods. The '536 patent relates to an electrosurgical system, [A398-400], whereas the '882 patent and '592 patent relate to methods of using an electrosurgical system to ablate and coagulate tissue in a target site, [A18631-33; A465-66].

A. The '536 Patent

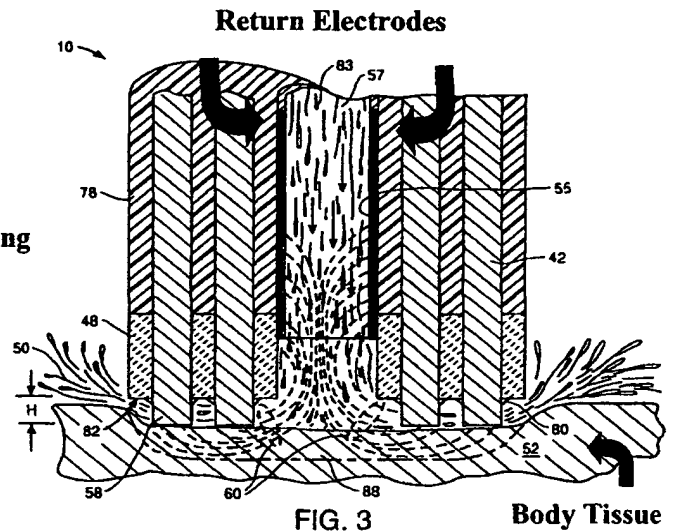
The system of the '536 patent includes a power supply, an electrically conducting fluid supply, and an electrosurgical probe having an electrode terminal (active electrode) and a return electrode. [A395-96 (10:35-42 & 11:54-12:10)]

Figure 1 shows the system.



During arthroscopic surgery, a surgeon inserts the probe into the surgical site that has been filled with electrically conducting fluid. He then brings an electrode terminal 58 on the probe's distal end into close proximity with the target tissue 52. [See A396 (12:23-40)] The return electrode 56 is circumscribed by an insulating

FIG. 2A



ArthroCare asserted claims 46, 47, and 56. [A370; A399-400 (18:29-36 & 19:11-15)] These claims depend from claim 45, which recites using electrically conductive fluid to generate a current path between the active and return electrodes that are coupled to a power supply with a connector:

a high frequency power supply;

an electrosurgical probe comprising a shaft having a proximal end and a distal end, an electrode terminal disposed near the distal end, and a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply;

a return electrode electrically coupled to the electrosurgical power supply; and

an electrically conducting fluid supply for directing electrically conducting fluid to the target site such that the electrically conducting fluid generates a current flow path between the return electrode and the electrode terminal.

[A399 (18:13-28) (emphases added)] Claim 46 additionally requires the return electrode to form a portion of the probe's shaft, [A399 (18:29-31)], like the device in Figure 8 of the Roos article and Figures 7 and 8 of the Roos patent. [A18723; A18675] Similar to the Roos device, claim 47 recites an insulating member circumscribing the return electrode, which is sufficiently spaced from the active electrode to minimize direct contact between the return electrode and the patient's tissue. [A399 (18:32-36)] Claim 56 recites that the target site is selected from a group of specific locations, including the abdominal cavity. [A400 (19:11-15)]

B. The '592 Patent

The '592 patent relates to a method of performing a surgical procedure by positioning an electrode terminal within an electrically conductive fluid near a target site, positioning the return electrode within the fluid away from the patient's tissue to create a current pathway through the fluid, and applying energy to target tissue (e.g., to ablate the tissue) with the electrode terminal. [A465 (24:6-21);

A454 (1:25-28)] Importantly, the claims require the return electrode not to contact body tissue at all during the claimed method. [A465-66 (24:6-21 & 25:43-54)]

ArthroCare asserted claims 1, 3, 4, 11, 21, 23, 26, 27, 32, and 42 of the '592 patent. [A374] Independent claims 1 and 23 both recite a specific set of method steps, during which the return electrode does not contact the body structure:

1. A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising: positioning an electrode terminal into at least close proximity with the target site in the presence of an electrically conductive fluid; positioning a return electrode within the electrically conductive fluid such that the return electrode is not in contact with the body structure to generate a current flow path between the electrode terminal and the return electrode; and

applying a high frequency voltage difference between the electrode terminal and the return electrode such that an electrical current flows from the electrode terminal, through the region of the target site, and to the return electrode through the current flow path.

23. A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising: contacting an active electrode with the body structure in the presence of an electrically conductive fluid;

spacing a return electrode away from the body structure in the presence of the electrically conductive fluid; and

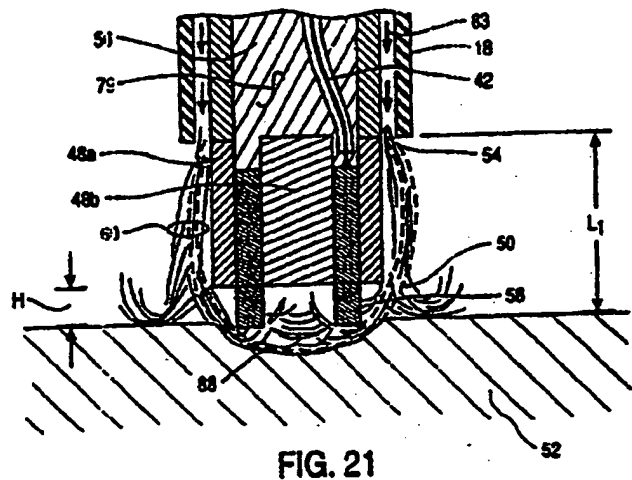
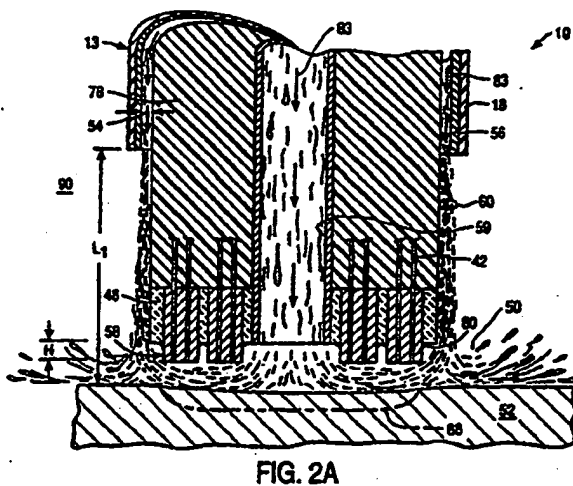
applying a high frequency voltage difference between the active electrode and the return electrode such that an electrical current flows from the active electrode, through the electrically conductive fluid, and to the return electrode.

[A465-66 (24:6-21 & 25:43-54) (emphases added)] Each of the other asserted claims depends from claim 1 or claim 23. [A465-66]

C. The '882 Patent

Similar to the '592 patent's method, the method of the '882 patent generally involves positioning an electrosurgical probe near a target site and applying a high frequency voltage between the active electrode(s) and the return electrode.

[A18621 (3:65-4:9)] The patent discloses embodiments having at least two active electrodes (e.g., Figs. 2-15 & 23), [A18604-11; A18618; A18627 (16:41-43)], and an embodiment having only one active electrode (e.g., Figs. 21-22), [A18617; A18629 (20:19-48)].



ArthroCare asserted claims 13, 17, and 54 of the '882 patent, [A372-73], which depend from independent claim 1.² After the '882 patent issued, ArthroCare obtained multiple certificates of correction, under 35 U.S.C. § 255, that alter the claim language. The August 25, 1998 certificate of correction ("Certificate of

² To the extent that claim 54 also may depend from claim 28, ArthroCare withdrew claim 54 and granted Smith & Nephew a covenant not to sue on it. [A14980-81]

Correction”) materially changes claim 1. [A18636-37] The claim 1 alterations are shown below (with additions underlined and deletions stricken):

1. A method for applying energy to a target site on a patient body structure comprising:
providing an electrode terminal [1] and a return electrode [2]
electrically coupled to a high frequency voltage source;
positioning the active electrode [3] terminal in close proximity to the target site in the presence of an electrically conducting ~~terminal~~ fluid;
and
applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

[Compare A18637 with A18631 (24:6-18)]

The originally-issued claim 1 recites at least three electrodes: an electrode terminal [1],³ a return electrode [2], and the active electrode [3]. [A18631] The corrected claim, in contrast, recites only two electrodes: an electrode terminal [1] and a return electrode [2]. [A18637] “Active electrode [3]” became “electrode terminal,” referring back to “electrode terminal [1].” Because the corrected claim recites fewer electrodes, the Certificate of Correction broadens claim 1 and makes the difference between infringement and noninfringement in this case.

³ The district court construed “electrode terminal” as “one or more active electrodes.” [A18]

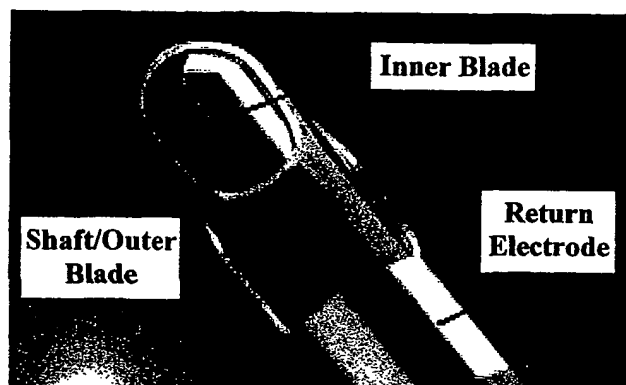
IV. Smith & Nephew's Products

Smith & Nephew, a global medical device company founded in 1856, develops and markets advanced medical devices to help physicians treat patients more effectively. ArthroCare accused three Smith & Nephew electrosurgical probes of infringement: the ElectroBlade Resector ("ElectroBlade"), the Saphyre Bipolar Ablation Probe ("Saphyre"), and the discontinued Dyonics Control RF System ("Control RF") products. [A45; A370-75] Each of the accused products must be inserted into electrically conductive fluid within a joint of the body before they may be used. [A15594 (1588:11-17); A15404 (1013-14); A15313-14 (776-79)]

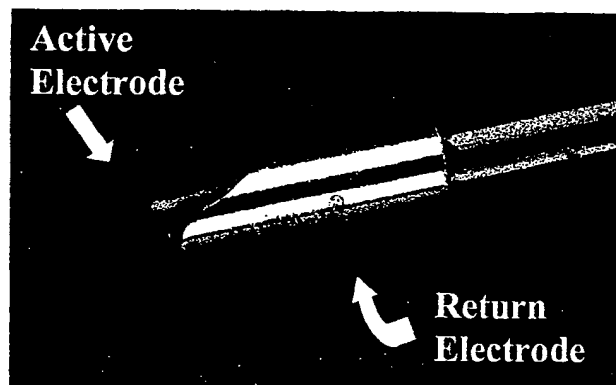
A. ElectroBlade

The ElectroBlade (shown below) has both cutting and coagulation features. To cut tissue, a hollow inner blade rotates past the edge of a hollow outer blade. Suction draws tissue into the gap between edges where the blades shear the tissue, much like scissor blades. [A45-46] To coagulate tissue, the inner blade acts as an active electrode. [A46] An insulating coating covers the outer blade, except for an opening at the distal end. [A46] Another hollow stainless steel tube, which acts as a return electrode, is attached outside of the insulated coating. [A46] Because the return electrode rests outside the inner and outer blades (wrapping completely around the probe) and is openly exposed at the distal end, it consistently contacts

tissue during normal use. [A5021; A26838-41; A26844-48; A26859-65; 15407-08 (1026:10-1029:5 & 1029:12-1030:23)] Because the return electrode is large, power is dissipated over a surface sufficiently large to avoid damaging tissue if contact between the return electrode and tissue occurs. [A15360 (963:15-966:10); A15253 (726:23-727:7); A15406 (1023:17-1024:25); A15408 (1030:15-23 & 1032:7-19); A26838-41; A26844-48]



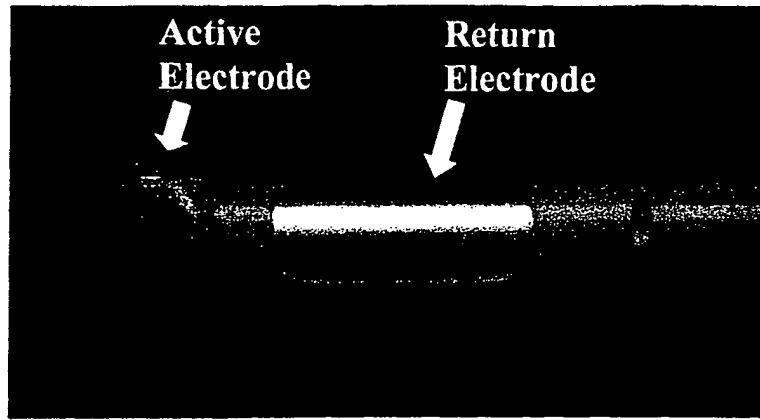
[A5020]



[A26840 (PX 113A)]

B. Saphyre

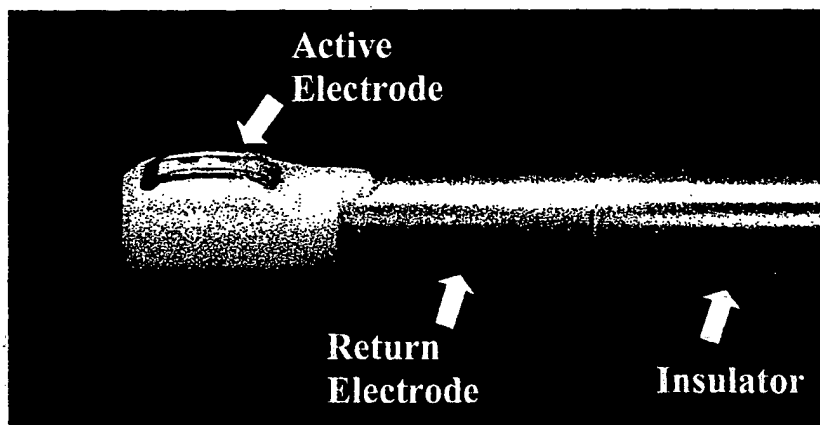
The Saphyre consists of a stainless steel shaft with a plastic handle and an active electrode at the distal end of the shaft. [A45; A26819-21; A26824-27] An insulating coating covers the shaft, except for the portion including the active electrode at the distal end and the large, exposed return electrode. [Id.]



[A26820 (DTX 572A)] Like the ElectroBlade, the return electrode is openly exposed and consistently contacts tissue during normal use, but its large size minimizes damage to tissue. [A5019; A15406 (1023:17–1024:25); A15360 (963:15-966:10); A15253 (726:4-13); A26819-21; A26824-27; A26859-65; A15360-61 (963:15-966:21, 968:24-969:4); A15398 (991:23-992:7)]

C. Control RF

Before it was discontinued in 2002, the Control RF consisted of a stainless steel shaft in a plastic handle, with a single active electrode at the distal end. [A46; A26829-31; A26835-36] The active electrode was a tungsten loop placed into a ceramic housing. [A5022; A26829-31; A26835-36; A15455-56 (1220:11-1223:23)]



[A26829 (DTX 574 (Control RF))] An insulating coating covered most of the shaft, except the portion closest to the active electrode, which is the large, exposed return electrode. [A46] Nothing prevented the return electrode from contacting tissue during normal use. [A5022]

V. Antitrust Counterclaim

Smith & Nephew counterclaimed against ArthroCare and Ethicon alleging an illegal restraint of trade in violation of section 1 of the Sherman Antitrust Act.⁴ [A311-12 (¶ 33-35, 37)] The restraint of trade arises from an agreement between direct competitors, ArthroCare and Ethicon (hereinafter “Agreement”). [A1469-1528]

A. Background

In 1998, ArthroCare charged Ethicon with patent infringement in a California district court. [A13261-62] The California court ruled that there were substantial invalidity questions as to the '536 and '882 patents. [A13276-80, A13285-87] ArthroCare and Ethicon settled the case before the court made a final ruling on the invalidity of the patents, {

}

⁴ Smith & Nephew's counterclaim also includes a separate allegation that ArthroCare knew the present suit was baseless. [A310-312 (¶ 30-31, 36)]

{

}

B. District Court Proceedings

Smith & Nephew's counterclaim alleges, inter alia, that ArthroCare and Ethicon entered into an agreement to restrain trade:

33. In the Settlement Agreement between ArthroCare and Ethicon ("the Settlement Agreement"), ArthroCare agreed, inter alia, {

}

34. Upon information and belief, ArthroCare and Ethicon settled the first ArthroCare litigation to prevent or restrain other competitors from entering the market

35. Upon information and belief, ArthroCare and Ethicon have at least a 75% share of the market in the United States for arthroscopic RF surgical devices, which is the relevant market for this antitrust claim. This combined market share of at least 75% gives ArthroCare and Ethicon substantial market power and the ability to restrain competition in the relevant market.

* * *

37. By conduct alleged herein, ArthroCare and Ethicon have entered into a combination or conspiracy in unreasonable restraint of trade in the relevant market in violation of Section 1 of the Sherman Act, 15 U.S.C. §1,

[A311-12 (¶¶ 33-35, 37)] Smith & Nephew also pled patent misuse as a defense.

[A305 (¶ 22)] The court stayed discovery and trial on the antitrust issues until after the patent trial. [A3336]

Soon after the patent trial, ArthroCare moved to dismiss Smith & Nephew's antitrust counterclaim under Fed. R. Civ. P. 12(b)(6). [A15912-13] Before Smith & Nephew's opposing brief was due, the court held a telephone conference in which it stayed all future proceedings, including briefing, on the antitrust issues.

[A16755 (12:12-24)] The court stated:

For the time being, we're going to stay the antitrust[,] damages and willfulness issues So for the moment, antitrust[,] damages, willfulness, stayed. We've got a briefing scheduled for all the other issues.

[A16755 (10:15-25); see also A16756 (15:2-5) (repeating that the antitrust claim is stayed)] When ArthroCare's counsel explained that a response to its motion to dismiss was due, the court again stressed that the antitrust issues (including briefing) were stayed. The court stated:

[E]verything is stayed and we'll deal with the antitrust issues later. That's what I said and that's what I mean. So the pending motion on antitrust is stayed and everything having to do with the antitrust counterclaims, discovery, substantive motions, et cetera, is stayed pending further order of the Court.

[A16756 (15:21-16:1)]

Ten months later, the court dismissed Smith & Nephew's antitrust counterclaim, [A32], mistakenly assuming that ArthroCare's motion was unopposed because Smith & Nephew did not respond to it. [A26 n.1] Having only one side of the story, the court also mistakenly accepted ArthroCare's mischaracterization of the counterclaim as based on only sham litigation allegations, ignoring the pleading's allegations regarding the ArthroCare/Ethicon agreement. [A28-29] After considering the legal standards for sham litigation, the court found that "the objective threshold for 'sham' litigation [was] not satisfied and that the Noerr-Pennington doctrine shield[ed] ArthroCare from liability."

[A31]

Smith & Nephew immediately requested reconsideration, reminding the court of its order barring a response. [A18275-80] Smith & Nephew explained, furthermore, that the alleged antitrust violation was the "illegal provisions in the ArthroCare/Ethicon license," and not only the current litigation against Smith & Nephew. [A18278-79)] The court denied reconsideration, stating that Smith & Nephew's reliance on "one statement from a June 2003 teleconference [regarding the stay was] misplaced." [A134 n.3] The court never addressed Smith & Nephew's argument that its counterclaim is based on the illegal Agreement rather than sham litigation. [A129-44]

SUMMARY OF THE ARGUMENT

The district court made several serious errors that led it to enter extraordinary relief—an injunction—without affording Smith & Nephew the opportunity to be heard on a complete defense to all of ArthroCare’s claims. This action has taken the Saphyre and ElectroBlade products out of the hands of surgeons, even though these products have unique features that make them superior to products offered by ArthroCare. [A16024-26; A16037-38; A16041-42]

First, the district court sustained a patent (whose validity the California district court questioned) by ignoring the clear and unambiguous disclosure of the Roos article and the Roos patent, each of which clearly and convincingly discloses all the claim limitations, including the recited “connector” and “electrically conducting fluid” limitations.

The district court further erred in dismissing Smith & Nephew’s antitrust counterclaim, which alleges that ArthroCare and Ethicon conspired to restrain trade through an illegal agreement in which Ethicon agreed, inter alia, {

} The court failed to recognize that this Agreement is beyond the reach of Noerr-Pennington immunity. This error resulted in part from the court’s decision to prevent Smith & Nephew from responding to ArthroCare’s

motion to dismiss, thus violating Smith & Nephew's due process rights. This violation alone requires this Court to vacate the dismissal.

Regarding the '592 patent, the district court was able to sustain the judgment of infringement only by failing to apply its own claim construction. Each asserted claim sets out a specific method and requires the return electrode not to contact the body at all during performance of the claimed method. Under this construction, if the return electrode ever touches the body during performance of the positioning steps or the energy application step, then the device does not infringe. During trial, the only evidence ArthroCare offered purporting to show actual practice of the claimed method were videos of the accused products. Even overlooking evidentiary problems associated with these videos, none of them showed practice of the complete claimed method without the return electrode contacting the tissue. To the contrary, the videos confirmed that the return electrode frequently contacts tissue during the positioning and energy application steps.

Regarding the '882 patent, ArthroCare's expert conceded that the accused products do not infringe claim 1, as originally issued. The jury found infringement, however, because it determined that the broadening Certificate of Correction is not invalid. Because the intrinsic evidence here is ambiguous as to the appropriate correction, the district court erred in denying Smith & Nephew's motion for judgment as a matter of law.

Accordingly, this Court should reverse the dismissal of Smith & Nephew's antitrust counterclaims, reverse the denial of judgment as a matter of law, and vacate the injunction.

ARGUMENT

I. Standards of Review

This Court reviews the dismissal of Smith & Nephew's antitrust counterclaim de novo. Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc., 171 F.3d 912, 919 (3d Cir. 1999); C&F Packing Co. v. IBP, Inc., 224 F.3d 1296, 1306 (Fed. Cir. 2000) (applying regional circuit law to Rule 12(b)(6) dismissal). A court may grant a Rule 12(b)(6) motion only if, after accepting all allegations as true and drawing all inferences, it is certain that the complainant cannot prove any facts to support the claim. Steamfitters, 171 F.3d at 919.

This Court reviews a denial of judgment as a matter of law de novo by reapplying the judgment as a matter of law standard. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998); Eddy v. Virgin Islands Water & Power Auth., 369 F.3d 227, 230 (3d Cir. 2004). Thus, this Court will reverse a denial of judgment as a matter of law "if the jury's factual findings are not supported by substantial evidence or if the legal conclusions implied from the jury's verdict cannot in law be supported by those findings." Cybor, 138 F.3d at 1454.

II. The '536 Patent is Invalid Because the Roos Article and the Roos Patent Each Anticipates the Asserted Claims

In the prior ArthroCare/Ethicon litigation, the California district court questioned the validity of claim 45 of the '536 patent, expressly finding that the Roos patent discloses every limitation of the claim and that the article discloses a bipolar device intended to be used in electrically conductive fluid. [A13276-77; A13279] ArthroCare and Ethicon settled that case, denying the district court the opportunity to remove this invalid patent from the public arena. ArthroCare escaped another invalidity ruling when both the jury and the district court disregarded the clear and convincing evidence⁵ that the Roos prior art anticipates the '536 patent.

A reference anticipates a claim if it discloses, either expressly or inherently, all of the claim's limitations. EMI Group N. Am., Inc. v. Cypress Semi Conductor

⁵ The district court erred in focusing on the fact that the Patent & Trademark Office ("PTO") considered the Roos prior art before issuing a notice of intent to publish a reexamination certificate on the '536 patent. [A78] The court mistakenly believed that this evidence alone "was sufficient to convince a jury of the validity of the '536 patent." [A78 (citing A15510 (1337-40))] The standard for proving invalidity, however, is the same for originally issued and re-exam issued patents. Superior Fireplace Co. v. Majestic Prods. Co., 270 F.3d 1358, 1367 (Fed. Cir. 2001). If a jury could blindly accept the PTO's determination of patentability—in the face of the clear and unambiguous disclosure of a prior art reference—no court could ever grant judgment as a matter of law of invalidity. Indeed, this Court would be powerless to remove an invalid patent from the public arena whenever a jury upheld its validity. In any event, the PTO has since instituted a second reexamination of all the asserted claims of the '536 patent, specifically questioning its validity over the Roos prior art. [A18215-21]

Corp., 268 F.3d 1342, 1350 (Fed. Cir. 2001); Cont'l Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). Thus, a reference still anticipates if a feature not expressly disclosed is necessarily present in the reference. Schering Corp. v. Geneva Pharms., 339 F.3d 1373, 1379 (Fed. Cir. 2003). Courts may rely on extrinsic evidence to determine whether the “missing” feature is necessarily present. Cont'l Can, 948 F.2d at 1268.

The Roos prior art discloses (1) using electrically conductive fluid to carry current between the active and return electrodes, (2) coupling the active and return electrodes to a power source with a connector located near the proximal end of the probe, and (3) circumscribing the return electrode, which is spaced from the active electrode to minimize direct contact between the return electrode and target tissue, with an insulating member. See supra Statement of Facts Section II.

At trial and during post-trial motions, ArthroCare focused on: “connector” and “electrically conducting fluid.” [A15509-37 (cross-examination); A15599-600 (closing arguments) A17937-40 (ArthroCare’s opposition to Smith & Nephew’s motion)]⁶ The district court denied Smith & Nephew’s motion, erroneously finding that the Roos prior art lacks the “connector” and “electrically conducting fluid” limitations. [A78-79]

⁶ ArthroCare did not call an expert to rebut Smith & Nephew’s invalidity evidence.

A. Connector

Claim 1 recites a “connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply.” [A462 (18:13-28)] The district court construed “connector” to mean “a structure that electrically links the electrode terminal to the high frequency power supply.” [A17]

1. The Roos Article and the Roos Patent Each Discloses the Recited Connector

Figure 9 of the Roos article, which is a photograph of the instrument illustrated in Figure 8 of the article, discloses a connector at its proximal end (far right):

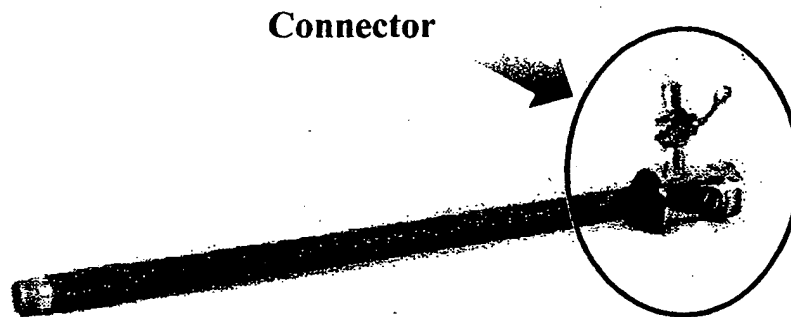


Bild 9: Photographie des Instrumentes aus Abbildung 8: Die Neutralelektrode sitzt als Metallring am Ende des Resektoskopschaftes.

Figure 9: Photograph of the instrument from Figure 8. The neutral electrode is positioned as a metal ring at the end of the resectoscope. [A18729]

[A18723; A18729 (Fig. 9 caption)] The active electrode “cutting loop” and the neutral return electrode are located at the distal end (far left) of the device.

[A18728-29; A18723] Both the active and the return electrodes are “connect[ed]” to “a high frequency generator” located outside the patient’s body. [A18728; see also A18720 (Fig. 1)]

As shown in Figure 8 (below), the active electrode “cutting loop” connects to wires or cables running toward the proximal end of the device. [A18723] Indeed, all of the wires shown in Figure 8 run toward the proximal end of the device.

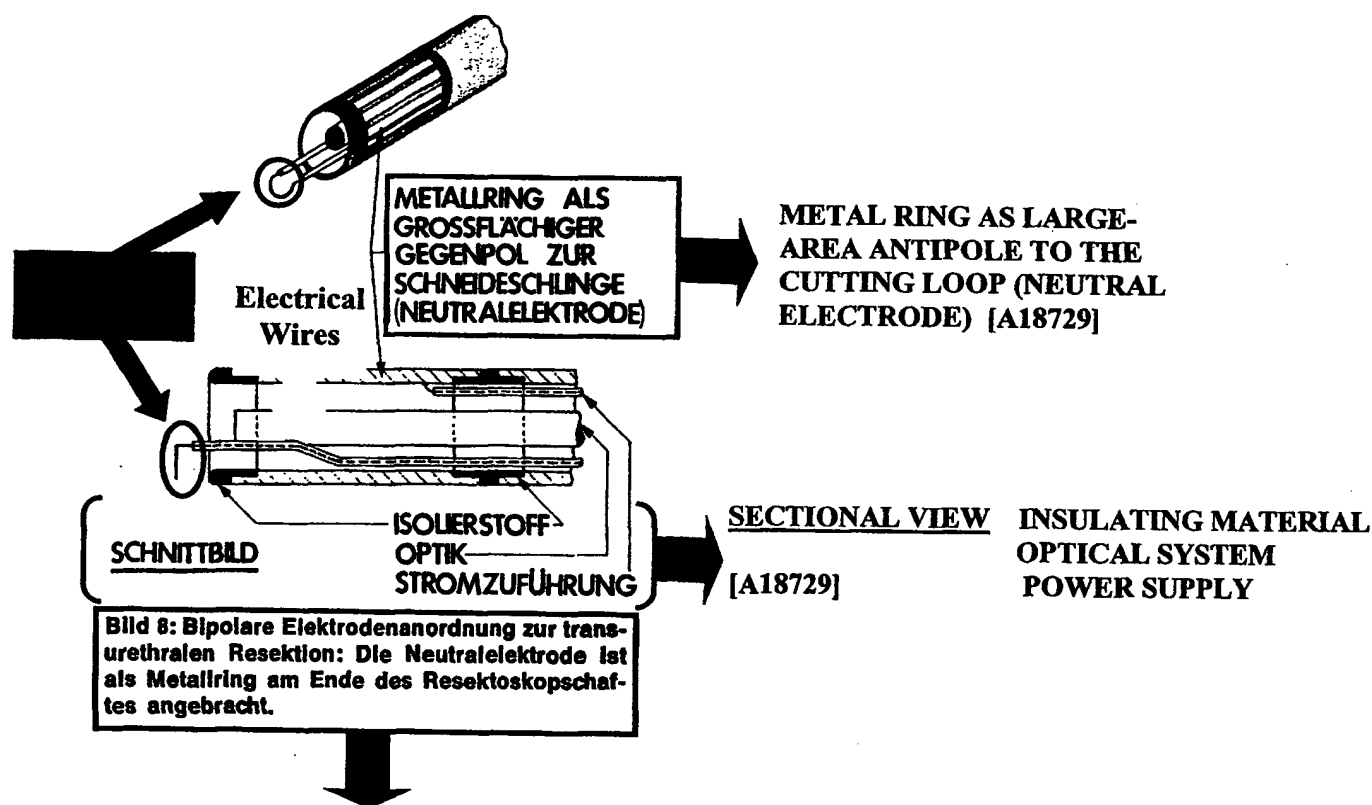


Figure 8: Arrangement of bipolar electrodes for transurethral resection. The neutral electrode is attached as a metal ring at the end. [A18729]

These wires run to the connector shown in Figure 9. [A18723] This connector joins the wires from the active and return electrodes to the high frequency

generator located elsewhere in the operating room. [A18723; A18720 (Fig. 1)] Thus, the connector is “a structure that electrically links the electrode terminal to the high frequency power supply.” [A15500 (1298:17-23); see also A15518 (1371:18-23 & 1372:8-13)]

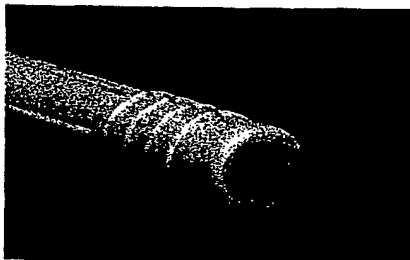
The device shown in Figures 8 and 9 of the article corresponds to the device shown in Figures 7 and 8 of the Roos patent. [A15517 (1365:4-18); A18723; A18675 (Figs. 7 & 8)] The patent figures and text disclose that the active electrode is connected to a high frequency generator through a connector located at the proximal end of the device. [A18671 (Abstract); A18676 (1:5-15 & 2:22-27); A18673 (Fig. 4); A18678 (5:2-10, 5:31-37, & 6:32-47); A18678-79 (6:67-7:7 & 7:21-28) (The electrical leads form a single cable “leading to the rear end of endoscope 13.”)] The Roos patent also claims a means—e.g., a wire—for connecting the electrodes to poles of a high-frequency generator. [A18679 (7:50-53, 8:49-54, & 8:36-39)] In light of this disclosure, the district court erred in concluding that the Roos patent does not disclose the location of the connector. [A78]

The district court also erroneously found that the Roos article does not explicitly describe the function for the connector structure located at the proximal end of the device in Figure 9. [A79] Although the Roos article does not have to describe “explicitly” every feature to anticipate the claims, see Schering, 339 F.3d

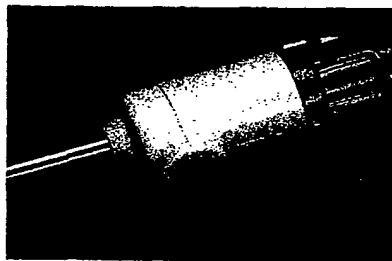
at 1379, because the article does describe using the instrument of Figure 9 to apply energy, it discloses the connector structure construed as “a structure that electrically links the electrode terminal to the high frequency power supply.” To justify its contrary conclusion, the court cited testimony from Smith & Nephew’s expert, Dr. Taylor. [A79 (citing A15500 (1298))] However, Dr. Taylor testified that the Roos article discloses two connectors, [A15500 (1298)], and this testimony certainly provides no basis to ignore the plain disclosure of the Roos article itself.

2. Claims Must Have the Same Scope for Both Validity and Infringement Analyses

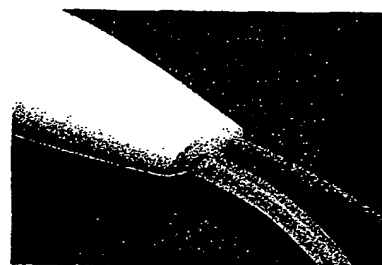
The district court’s construction is so broad that it includes all electrical conductors, even wires. ArthroCare urged this broad construction, [A3580], to ensnare the accused products within the claims’ scope. It is undisputed that the accused products and the Roos device (shown below) are coupled to their power supply with wires and do not include separate structures that anyone skilled in the art would consider to be “connectors,” if that term is construed properly.



Saphyre
[A26828 (PX 544)]

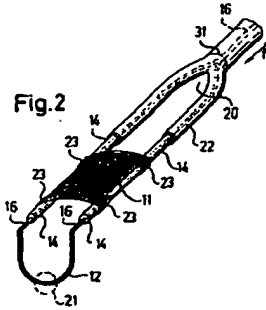


ElectroBlade
[A26842 (PX 113A)]



Control RF
[A26833 (DTX 574)]

Roos Patent [A18672]



ArthroCare cannot have it both ways. If the connector limitation is absent from the Roos devices, then it must also be absent from each of the accused products, and this Court should reverse the construction of “connector” and enter judgment that Smith & Nephew does not infringe.⁷ See Intervet Am., Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1053 (Fed. Cir. 1989) (Claims must be given the same construction when considering infringement as when considering validity.).

B. Electrically Conducting Fluid

The district court construed “electrically conducting fluid” to mean “any fluid that facilitates the passage of electrical current.” [A18] The Roos article discloses a bipolar device having a “fluid that facilitates the passage of electrical current.” [A18] The article discloses:

The high-frequency current . . . flows directly from the active cutting electrode, through the tissue to be cut and the irrigation liquid, to the annular neutral electrode”

⁷ Below, Smith & Nephew urged a more narrow interpretation of “connector,” based on the intrinsic record, as a removable mating structure. [A4054-59; A8074-77; see also A381; A383; A392 (4:13-20); A393 (6:31-34); A395 (10:47-51).] ArthroCare successfully convinced the district court to adopt the broader “wire” definition of connector. The Roos prior art and the accused devices all use a wire for this purpose. If ArthroCare now urges a narrower the definition of “connector” to avoid invalidity, there is no infringement for the same reasons.

[A18731 (emphases added); see also A18728 (current flows to the neutral return electrode through the irrigation liquid)] This straightforward statement is clear—electrical current passes through the irrigation liquid to the neutral return electrode. [see also A15500 (1299:6-11) (Dr. Taylor testifying that the article discloses electrically conducting fluid)]

Figures 6 and 7 of the article also depict current flowing through this liquid to the return electrode. [A18722; see also A18672 (Fig. 2)] The caption of Figure 6 states that “current flows from the cutting loop directly to the nearby . . . neutral electrode.” [A18728 (emphasis added)] In Figures 6 and 7 (see below), the return electrode—which is the metal plate located above the cutting loop—is suspended in the irrigation liquid without any tissue contact. [A18722; A18728]

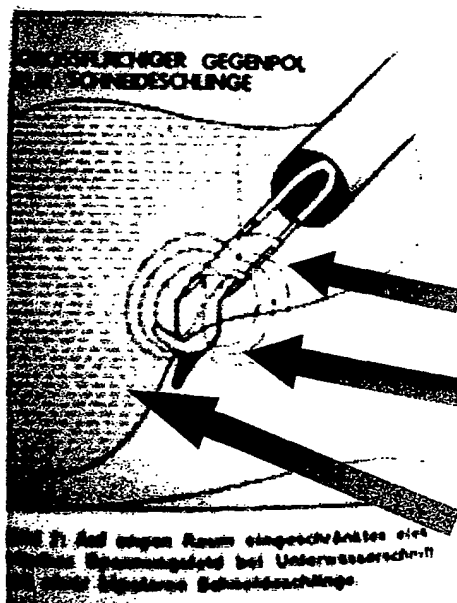


Figure 7: Electrical voltage field limited to a restricted area, during cutting with a bipolar cutting loop under water. [A18728]

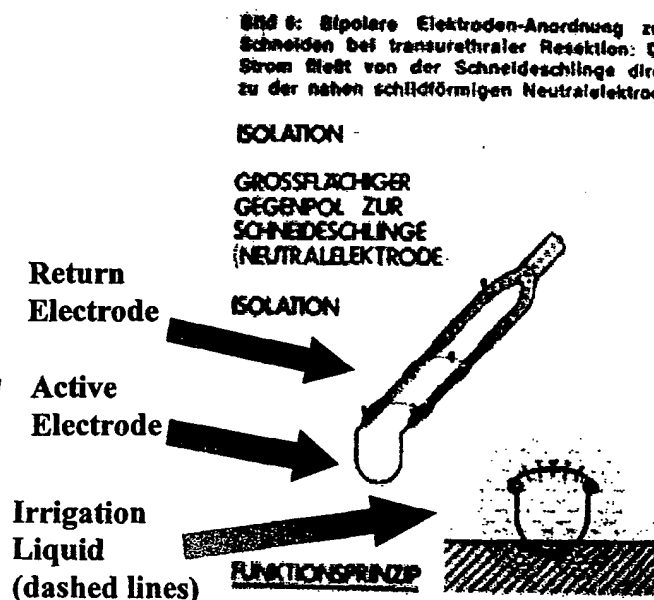


Figure 6: Bipolar electrode arrangement for cutting in the case of transurethral resection: The current flows from the cutting loop directly to the nearby lamelliform neutral electrode. [A18728]

Thus, the current reaches the return electrode only by flowing through the liquid. In other words, the “low resistance,” [A18278], path through the liquid “facilitates the passage of electrical current,” [A18], to the return electrode. [A18728-29; see also A18679 (7:59-62)] The Roos patent similarly discloses a liquid that facilitates the passage of electrical current. [A15501 (1303:9-21); A18679 (7:59-62) (“a space . . . adapted to be filled with liquid to provide electrical conductance between said electrodes”)]

Faced with this clear and convincing disclosure, ArthroCare misled the court and the jury by highlighting irrelevant portions of these references. For the article, ArthroCare focused on monopolar devices (i.e., devices whose return electrode is outside the patient’s body), which are not at issue in this case, and the allegedly non-conducting liquid used with them. [A79 (citing A15510-11, where Dr. Taylor discussed the Roos patent)] Even if the Roos article discloses an allegedly non-conductive liquid⁸ used with monopolar devices in addition to the electrically conducting liquid used with bipolar devices, this disclosure would not negate the definitive statements that current “flows directly from the active cutting electrode, through . . . the irrigation liquid, to the annular neutral electrode” [A18731;

⁸ Under the court’s construction of “electrically conducting fluid”—i.e., “any fluid that facilitates the passage of electrical current” [A18]—this so-called “non-conductive” fluid, which ArthroCare admits carries current [A15510 (1340:6-10)], also qualifies as the recited electrically conducting fluid.

A18728] The article itself thus provides clear and convincing evidence of the recited “fluid that facilitates the passage of electrical current.”

Regarding the patent, ArthroCare focused on a single embodiment (Figure 5) of the Roos patent, on which Dr. Taylor did not rely for his opinion regarding the electrically conducting fluid. [A79; A15512 (1345:18-20)] Neither ArthroCare nor the court addressed claim 1’s disclosure of “a space . . . adapted to be filled with liquid to provide electrical conductance between said electrodes.” [A18679 (7:59-62)]. The Roos patent itself thus provides clear and convincing evidence of the recited “fluid that facilitates the passage of electrical current.”

Finally, ArthroCare argued that the Roos prior art does not disclose saline or Ringer’s lactate (two specific kinds of electrically conducting fluids). [A79 (court’s opinion citing A15510-11)] Because the ’536 patent requires only “electrically conducting fluid”—not saline or Ringer’s lactate—the court erred in relying on this distinction.

C. The Roos Prior Art Includes the Other Disputed Limitation

Even though ArthroCare challenged the prior art’s disclosure of the “return spaced from the electrode terminal” limitation of claim 47 at trial, the court did not deny Smith & Nephew’s motion on this basis. This omission is no surprise, however, because both the Roos article and the Roos patent disclose an insulating

member circumscribing the return electrode, and the return electrode being spaced from the active electrode.

The Roos device of Figures 8 and 9 of the Roos article and Figures 7 and 8 of the Roos patent show insulating rings circumscribing the return electrode. [A18723 (see “ISOLIERSTOFF” arrows); A18729 (Fig. 8 caption identifying “insulating material” circumscribing the neutral electrode); A18679 (7:8-20) (“insulating rings 35, 36” mount to the neutral return electrode); A18675 (Figs. 7 & 8)]. The figures also show that the return electrode 11 is sufficiently spaced from the active electrode 12. Dr. Taylor likewise testified that these insulating rings constitute “insulating members,” [A15501 (1304:13-18); A15512 (1347:20-21); A18679 (7:8-20)], and that the return electrode shown in these figures is sufficiently spaced from the active electrode cutting loop, [A15501 (1304:21-1305:2); A15512 (1346:23-1347:22) (testifying that the resectoscope in the Roos article moves out from the return electrode by “about an inch”)].

The Roos prior art thus undeniably discloses each of the limitations of the asserted claims. Accordingly, the court erred in denying Smith & Nephew’s motion for judgment as a matter of law that the ’536 patent is invalid.

III. The District Court Erred in Dismissing Smith & Nephew's Antitrust Counterclaim

A. The District Court's Procedural Error Requires This Court to Vacate the Dismissal

Smith & Nephew brought its antitrust counterclaim to redress an illegal conspiracy between ArthroCare and Ethicon—{

}—that arose after the California district court found the ArthroCare patents likely to be invalid over, inter alia, the Roos prior art. [A308-12 (¶¶ 15-18, 32-37)]

In its haste to remove this case from its docket, the district court violated Smith & Nephew's due process rights in dismissing the counterclaim without allowing Smith & Nephew to respond to ArthroCare's motion to dismiss. A district court must give a plaintiff "at least, the opportunity to submit a short written statement in opposition to the motion" before dismissing a claim under Rule 12(b)(6). Jordan v. County of Montgomery, Pa., 404 F.2d 747, 748 (3d Cir. 1969); see also Dougherty v. Harper's Magazine Co., 537 F.2d 758, 761 (3d Cir. 1976) ("[A] Rule 12(b)(6) motion for dismissal . . . may be disposed of only after a hearing, which affords an opportunity to present legal arguments either orally, in writing, or both at the District Court's discretion."); see also Neitzke v. Williams, 490 U.S. 319, 329-30 (1989).

Here, the court prevented Smith & Nephew from responding to ArthroCare's motion and then, incredibly, penalized it for the lack of response. [A26 n.1] The court stayed all future proceedings on the antitrust counterclaim "until further Order of the Court." [A16755 (10:15-25, 12:23-24); A16756 (15:2-16:3)] Because the court denied Smith & Nephew an opportunity to respond, its dismissal of the antitrust counterclaim clearly was improper. This procedural error alone requires this Court to vacate the dismissal. Jordan, 404 F.2d at 748.

B. Because the Counterclaim States a Claim, the Court Substantively Erred in Granting the Motion to Dismiss

The court's procedural error was particularly harmful because it allowed ArthroCare to mischaracterize the antitrust counterclaim as based merely on allegations of sham litigation. Without the benefit of a response brief, the court overlooked the allegations that ArthroCare and Ethicon—{

} [See A311-

12]

The district court was required to accept these allegations as true to determine whether ArthroCare met its burden to prove that Smith & Nephew failed to state a claim. See Steamfitters, 171 F.3d at 919. At the motion to dismiss stage, Smith & Nephew is not required to prove its case conclusively. Indeed, "in

antitrust cases, where the proof is largely in the hands of the alleged conspirators, dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly.” Hosp. Bldg. Co. v. Trs. of Rex Hosp., 425 U.S. 738, 746 (1976) (internal quotation and citation omitted).

**1. Noerr-Pennington Does Not Apply to the ArthroCare/
Ethicon Agreement**

The district court dismissed Smith & Nephew’s antitrust counterclaim by relying upon ArthroCare’s argument that it was immune from antitrust liability under the Noerr-Pennington doctrine. [A28-31, A134-35] Focusing solely on Noerr-Pennington constitutes reversible error.

Although this immunity extends to some conduct incidental to the prosecution of a lawsuit, Globetrotter Software, Inc. v. Elan Computer Group, Inc., 362 F.3d 1367, 1375-77 (Fed. Cir. 2004), it does not apply to all litigation-related activity, such as a settlement agreement that creates an illegal restraint of trade, Andrx Pharms., Inc. v. Bioval Corp., Int’l, 256 F.3d 799, 817-818 (D.C. Cir. 2001) (holding that an agreement to pay a competitor to refrain from entering the market was not protected by Noerr-Pennington, even though the agreement settled litigation). The district court should have examined Smith & Nephew’s substantive allegations to determine whether the counterclaim states a claim.

2. The ArthroCare/Ethicon Agreement Is an Unreasonable Restraint of Trade

Under Section 1 of the Sherman Act, “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraining of trade or commerce . . . is . . . illegal.” 15 U.S.C. § 1 (1994). “Three elements must be alleged to sustain a cause of action under section 1 of the Sherman Act . . . a contract, combination or conspiracy; a restraint of trade; and an effect on interstate commerce.” Fuentes v. S. Hills Cardiology, 946 F.2d 196, 198 (3d Cir. 1991); see also Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1068 (Fed. Cir. 1998) (choice of law). To determine whether an agreement is an unreasonable restraint of trade, one must examine whether it enhances or impairs competition. Cal. Dental Ass’n v. Fed. Trade Comm’n, 526 U.S. 756, 779-80 (1999).

A patent licensing or settlement agreement may be an unreasonable restraint of trade if it is part of a plan to restrain competition. See, e.g., United States v. Singer Mfg. Co., 374 U.S. 174, 189 n.7, 192-94 (1963) (finding an antitrust violation based in part on cross-license and agreement to settle an interference to prevent challenges to validity and to exclude Japanese competitors from the market through enforcement of patents); United States v. New Wrinkle, Inc., 342 U.S. 371, 378 (1952) (“Patents give no protection from the prohibitions of the Sherman Act . . . when the licenses are used . . . in the scheme to restrain [trade].”); In re Yarn Processing Patent Validity Litig., 541 F.2d 1127, 1137 (5th Cir. 1976)

(finding that “arrangements made with non-patentee competitors to fix royalties charged by the patentee or to allow the patentee to turn over to competitors a fixed compensation collected from customers of the competitors under the guise of sharing royalty income” violated section 1); In re Buspirone Patent Litig., 185 F. Supp. 2d 363, 366, 378-79 (S.D.N.Y. 2002) (denying 12(b)(6) motion to dismiss antitrust claim based on settlement agreement that paid one party to stay out of the market and withdraw its validity challenges).

After a California district court questioned the validity of ArthroCare’s patents, ArthroCare and Ethicon executed the Agreement to settle the case.

[A1469-1528, A13276-80, A13285-87] {

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} This Court

recognizes a significant public policy interest in removing invalid patents from the public arena. See, e.g., Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 100-102 (1993); Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 349-50 (1971); United States v. Glaxo Group Ltd., 410 U.S. 52, 57-58 (1973); Nestier Corp. v. Menasha Corp.-Lewisystems Div., 739 F.2d 1576, 1581 (Fed. Cir. 1984).

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} 374 U.S. at 199

(White, J., concurring). Justice White concluded that this agreement alone demonstrated an antitrust violation:

“[C]ollusion to secure a monopoly grant runs afoul of the Sherman Act’s prohibitions against conspiracies in restraint of trade—if not bad per se, then such agreements are at least presumptively bad. . . . The patent laws do not authorize, and the Sherman Act does not permit, such agreements between business rivals to encroach upon the public domain and usurp it to themselves.”

Id. at 200.¹⁰

¹⁰ {

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} [See, e.g., A311 (¶ 34)]

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¹¹ {

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Under the facts alleged in Smith & Nephew's counterclaim, therefore, the Agreement insulates ArthroCare and Ethicon—who already share a dominant position in the market—from competitive pressures and enables them to charge prices above a competitive level. Accordingly, Smith & Nephew stated a claim upon which relief may be granted.

C. This Court Should Vacate the Injunction

The district court thus erred both procedurally and substantively in granting ArthroCare's motion to dismiss the antitrust counterclaim. Until this counterclaim is adjudicated on the merits, the enforceability of ArthroCare's patents is in serious doubt. Indeed, the district court understood that, while the antitrust counterclaim was still pending, an injunction was premature. [A123, n.29 ("For this reason [the antitrust counterclaim no longer pending], the court concludes that it is not premature to issue a permanent injunction at this time.")]

The antitrust counterclaim, once proven, is a complete defense to ArthroCare's infringement claims because these allegations also constitute a form of patent misuse. Smith & Nephew plead patent misuse as a defense to ArthroCare's infringement claim. [See A305 (¶ 22)] "[A] patentee who uses a patent to violate the antitrust laws is guilty of patent misuse" Hunter Douglas, Inc. v. Comfortex Corp., 44 F. Supp. 2d 145, 156 (N.D.N.Y. 1999); see also Ansul Co. v. Uniroyal, Inc., 448 F.2d 872, 879-80 (2d Cir. 1971) (upholding finding that antitrust violations constituted patent misuse, rendering the patent unenforceable). As with antitrust violations, patent misuse activity may be per se misuse or misuse under a rule of reason, the latter of which requires a court to examine whether the questioned practice imposes an unreasonable restraint on competition. Va. Panel Corp. v. MAC Panel Co., 133 F.3d 860, 869 (Fed. Cir. 1997). Thus, if Smith & Nephew prevails on the antitrust counterclaim, it will also prove its misuse defense. "A successful patent misuse defense results in rendering the patent unenforceable until the misuse is purged." Senza-Gel Corp. v. Seiffhart, 803 F.2d 661, 668 n.10 (Fed. Cir. 1986).

Accordingly, if this Court vacates or reverses the dismissal, it should also vacate the injunction.

IV. No Substantial Evidence Supports a Finding That Smith & Nephew Infringes the '592 Patent Under the Proper Claim Construction

A. There is No Literal Infringement Under the Court's Claim Construction

In arguments to the jury and in post trial motions, ArthroCare successfully convinced the jury and the district court to disregard the claim construction.¹² This critical error led the court to conclude erroneously that the evidence supports a finding of literal infringement.

1. The Court's Construction Requires That the Return Electrode Does Not Contact the Body Structure at All During the Claimed Method

Each of the '592 patent claims recites that the return electrode either is "not in contact with the body structure" or is spaced "away from the body structure." Claim 47 of the '536 patent also recites this limitation.¹³ [A399 (18:32-36)] The district court construed these two phrases to require that the return electrode not contact the body at all during the claimed method.

The claim limitation . . . is clear—the return electrode is not to contact the body at all during the performance of the claimed method. The claimed method does not contain any time limitations. Thus, the claimed method is performed when each of the three steps of the claim has been completed.

¹² To the extent that ArthroCare's arguments convinced the district court to modify its claim construction, Smith & Nephew asks this Court to review and reform that construction consistent with the original Markman ruling in this case.

¹³ Because this same limitation exists in claim 47 of the '536 patent, Smith & Nephew asks that infringement of this claim be evaluated along with the '592 claims.

[A340 (emphasis added); A17]

The claimed method involves three specific and related steps—two “positioning” steps and one “application of energy” step. [A434-66 (24:9-21 & 25:43-54)] Under the court’s construction, a device literally infringes only if the return electrode does “not contact the body at all” during all three steps.

The claims set forth the exact requirements for each step of the method. Step one requires the surgeon to position an electrode terminal in close proximity to a target tissue site in the presence of electrically conductive fluid. [A465-6 (24:9-11 & 25:46-47)] This step thus requires the electrode terminal to be moved into a location adjacent to the target tissue and conductive fluid to be provided at the site.

The second step requires the surgeon to position a return electrode within the electrically conductive fluid. [A465-6 (24:12-16 & 25:48-49)] This step carries two significant limitations: (1) the surgeon must position the return electrode so that it does not contact the patient’s body, and (2) the electrically conductive fluid must create a current flow path between the electrode terminal and the return electrode. The patent stresses that arranging the electrodes in this manner prevents any adjacent tissue from being damaged by the return electrode. [A455 (4:25-28); A462 (17:47-54)]

In step three, the surgeon must apply a high frequency voltage difference between the electrode terminal and the return electrode to induce current to flow from the terminal, through the region of the target site, and through the fluid current flow path, to the return electrode. [A465-6 (24:17-21 & 25:50-54)] Because the claim requires current to flow through the fluid current flow path, rather than through solely the tissue, the separation between the return and the patient's tissue established in the earlier steps must be maintained throughout the recited method. Id.

The Markman ruling holds that the return electrode must not contact the patient's body "at all" during the entire method. If the return electrode touches the body during performance of the positioning steps or the energy application step, then the device does not infringe. ArthroCare had asked for a construction under which a device would infringe if the return broke contact with the body structure for only a moment during use. [A4130; A14063-64] The court expressly rejected ArthroCare's proposed construction. [A4130; A14063-64] ArthroCare's proposal ignored significant limitations of the method that require the return electrode to be positioned away from the patient's body to create a current flow path through the fluid, and this separation flow path to be maintained and used during the energy

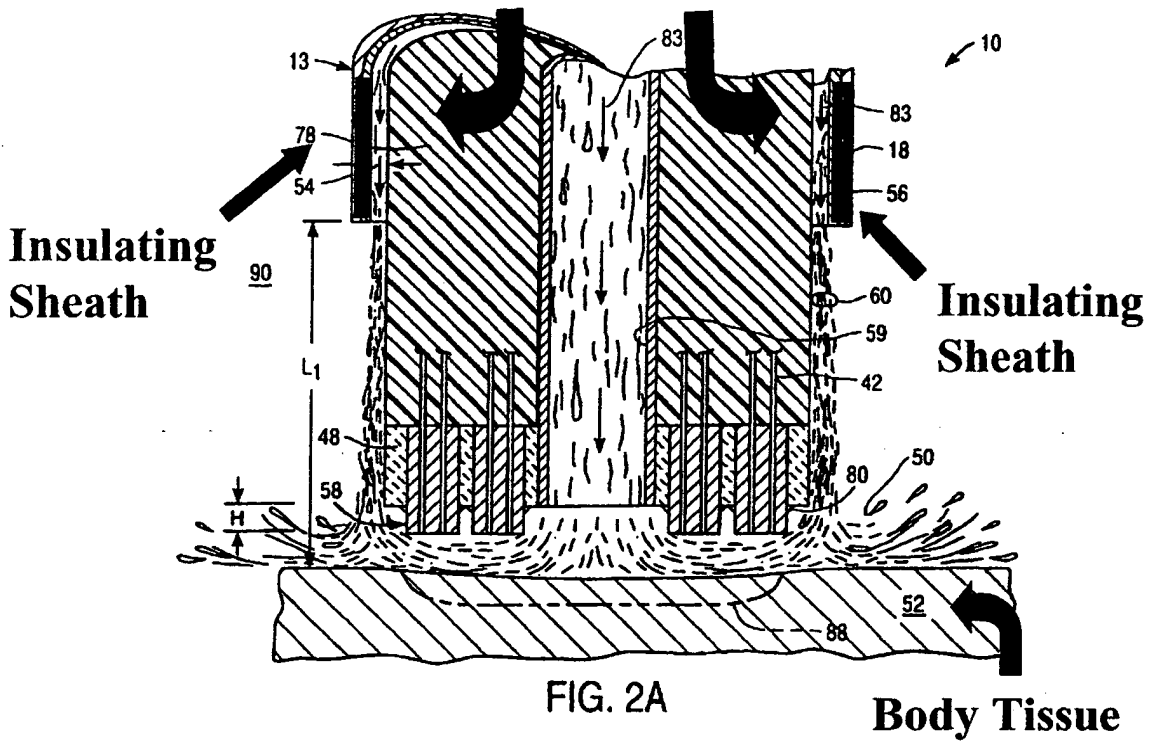
application step.¹⁴ A single moment in time does not reflect the continuing character of the method or the requirement for the separation spacing to be maintained throughout the method.

Notwithstanding this plain language, ArthroCare convinced both the jury and the district court to disregard the Markman construction and allow a short or sporadic break in contact between the return and the body structure to satisfy the claims. [See A15592-93 (1580:17 – 1584:7)] The whole of the intrinsic record supports the original construction. As noted above, the claim language is not satisfied by a momentary break in contact between the patient's body and the return electrode, but, rather, requires no contact during the entire method.

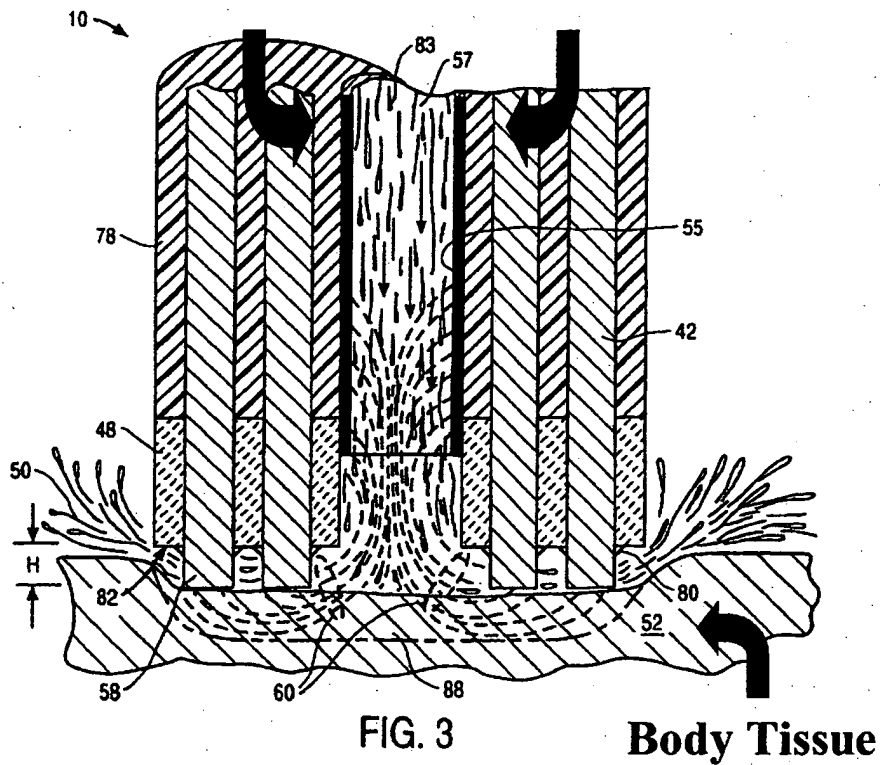
The written description warns that touching a patient's body with an exposed return electrode will cause tissue damage. [A434-66 (1:66-2:6)] To prevent this type of damage, the '592 patent teaches to space the return electrode away from the active electrode and enclose it within an insulating sheath to ensure no contact. [A434-66 (4:22-28; 17:43-54; 18:64-66; 19:21-26; 19:11-13; Fig. 2A)] Alternatively, the patent teaches placing the return electrode inside an inner lumen

¹⁴ Claim 1 recites (1) "positioning a return electrode within the electrically conductive fluid such that the return electrode is not in contact with the body structure to generate a current flow path between the electrode terminal and the return electrode" and (2) "applying a high frequency voltage difference . . . such that an electrical current flows from the electrode terminal, through the region of the target site, and to the return electrode through the current flow path." [A465 (24:12-21) (emphases added); see also A466 (25:48-54) (similar language in claim 23)]

Return Electrodes



Return Electrodes



to prevent contact with body tissue. [A434-66 (18:26-31 & Fig. 3)] Figures 2A and 3 show the return electrodes as illustrated in the '592 patent (see facing page). The specification never suggests that sometimes contacting and damaging tissue with the return would be acceptable.

The prosecution history also supports the court's "no contact" construction. ArthroCare added the "not in contact/spaced away" limitations during prosecution to overcome multiple anticipation rejections based on prior art that showed contact between the return and the patient's body. [A20498-504; A20533-43] ArthroCare argued that during the claimed method—i.e., all three steps—the return electrode is spaced away from the tissue:

in performing electrosurgery according to the method of claim [1], the active and return electrodes of the instrument are both positioned near a tissue site in the presence of electrically conductive fluid The return electrode is spaced away from the tissue such that electric current flows from the active electrode, through the conductive fluid, to the return electrode.

[A20556 (emphases added)] Notably, ArthroCare did not argue that the return electrode could contact tissue occasionally or sporadically. Instead, ArthroCare flatly distinguished its invention from the prior art because the prior return electrodes made contact with the body structure. Therefore, the court properly rejected ArthroCare's attempt to rewrite the claims to limit the time necessary for the "not in contact" limitation and the original construction should be upheld and actually applied.

2. The Record Evidence Compels Judgment of Noninfringement

At trial, ArthroCare convinced the district court and the jury to abandon the Markman “not in contact at all” construction in favor of one where any break in contact was sufficient. ArthroCare had no choice—the evidence of actual use of the accused devices failed to prove that the return electrode does not contact the body at all during the claimed method.¹⁵ In fact, the evidence amply demonstrates that the return electrodes of the accused devices frequently contact tissue during use.

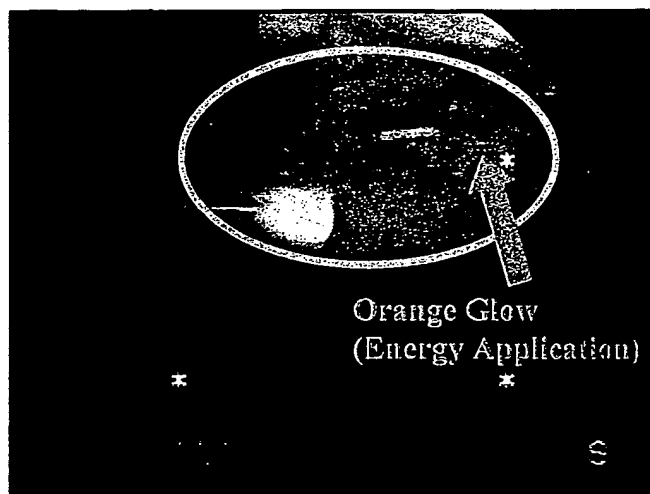
The only direct proof of the use of the accused devices in the record are videos admitted into evidence at trial. [A19249; A19254; A20067; A22539] Each video shows movement of the probe, although the record is silent as to whether the movement corresponds to the specific positioning steps required by the claims. Occasionally, the videos seem to indicate that the probes apply energy,¹⁶ but the evidence does not indicate whether the user is practicing the entire method—i.e., positioning the electrode terminal near the target site, positioning the return electrode within the electrically conductive fluid to create a space between the return electrode and the patient’s body and thus a current flow path, and then

¹⁵ Just prior to trial, the district court found that several structural elements were present in the Saphyre device. [A14064-65] The court later clarified that these findings were collateral and not binding on the issues for trial. [A15039]

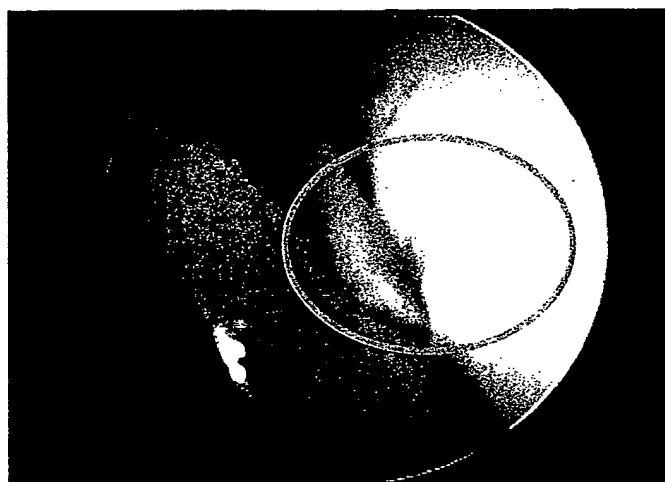
¹⁶ The presence of an orange glow, bubbles, or charring indicates that energy is being applied to the device. [A15407 (1027:7-1028:25); A15361 (968:8-25)]



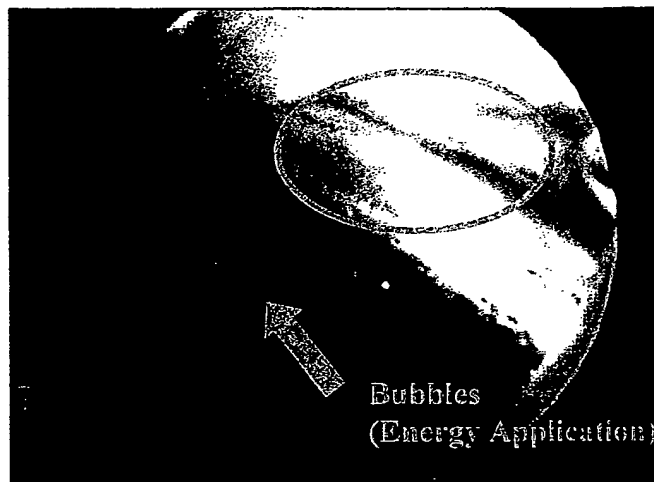
PX 105: Saphyre (Choti2.mpg)



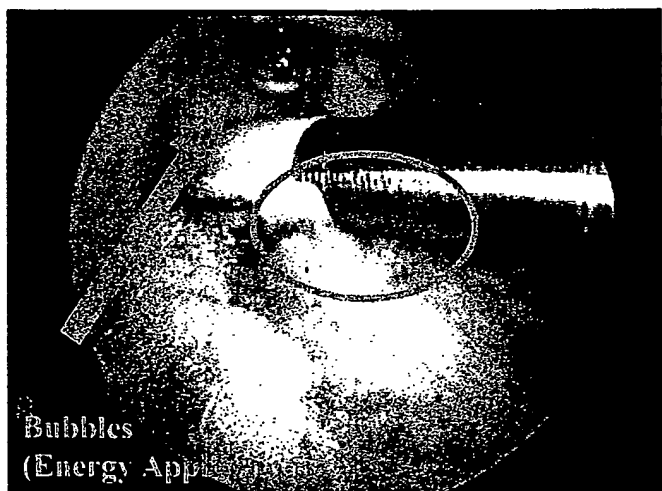
DTX 315: Saphyre (BP-90S SAD 2-24sec.mpg)



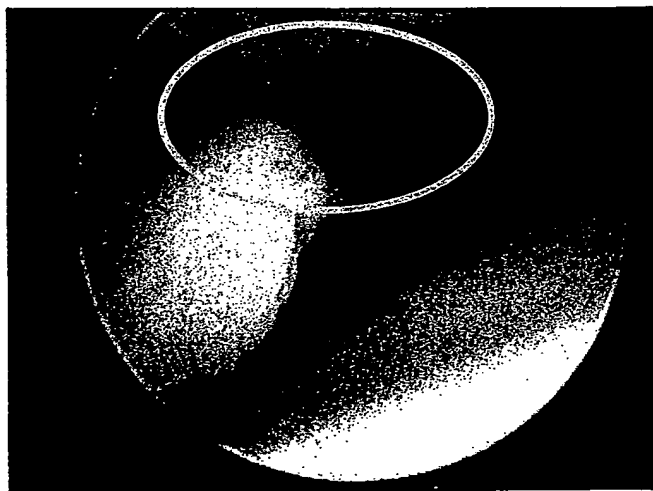
DTX 316: ElectroBlade (E-Blade Dr Cole Coagulation.mpg)



DTX 316: ElectroBlade (E-Blade Dr Cole Coagulation.mpg)



PX 105: Control RF (Choti8.mpg)



DTX 897: Control RF (Tuft's Lab.mpg)

applying energy across the target site, through the fluid filling this space—all without having any contact between the return electrode and the body structure.

The videos simply show movement of the probes within the very tight confines of arthroscopic procedures and the occasional application of energy to tissue.¹⁷ They do not show that the return electrodes of the accused products are not in contact “at all” with the patient’s body during use. To the contrary, they show that the return electrode frequently contacts tissue during movement of the probe. [A19249; A19254; A20067; A22539; A15407-08 (1025:6-1032:19)] Snapshots of the admitted videos are reproduced on the facing page and in the appendix with yellow ovals added to highlight tissue contact. [A26858-65] As the snapshots demonstrate, the videos conclusively show that the return electrode contacts tissue during normal operation of the devices.

The testimony of multiple trial witnesses reinforced this point to the jury. For example, Ms. Drucker, the ElectroBlade project manager, and Ms. Knudsen, the Saphyre project manager, each testified that the return electrode contacts tissue during the positioning and energy application steps. [A15360-61 (963:15-966:21; 968:24-969:4); A15455-56 (1220:11-1223:23); A15398 (991:23-992:7); A15407-08 (1026:10-1029:5; 1029:12-1030:23)] Dr. Taylor also testified that the return

¹⁷ Many of the videos upon which ArthroCare relied were not patient procedures, but were animal or cadaver subjects, which do not meet the claims’ basic requirement that the method is used to treat patients.

electrode contacts tissue during the positioning and energy application steps. [A15455-56 (1220:11-1221:4)] Dr. Choti, another Smith & Nephew expert, further testified that the return electrode “frequently contacted the tissue within the joint capsule.” [A15253 (725:4-9; 726:23-727:7)] ArthroCare does not dispute these facts. Indeed, ArthroCare’s expert and its trial counsel admitted that the return frequently contacts tissue during use of the accused devices. [A15155-57 (422:14-423:5); A15593 (1583:20-1584:7)] Even though this testimony may also indicate that the contact is occasionally broken, this testimony does not demonstrate that the entire method is practiced before contact is re-established.

ArthroCare’s failure to introduce infringement evidence was not an oversight. The problem ArthroCare faced is that the accused devices were designed using a fundamentally different approach: rather than separate the return electrode from the body at all times, the accused products use a larger return electrode to reduce current density, which minimizes damage caused by contact. [A15360 (963:15-966:10); A15253 (726:4-727:7); A15406 (1023:17-1024:25); A15408 (1030:15-23 & 1032:7-19); A26838-41; A26844-48; A26819-21; A26824-27; A26829-31; A26835-36] In the patent, ArthroCare repeatedly emphasized the importance of preventing its small return electrode from contacting tissue to prevent damage:

[t]he return electrode is spaced from the active electrode and enclosed within an insulating sheath. This minimizes exposure of the return

electrode to surrounding tissue and minimizes possible shorting of the current between the active and return electrodes.

[A455 (4:25-28); see also A454 (1:66-2:6)] By avoiding direct contact, the claimed invention avoids unwanted tissue necrosis. [A462 (17:47-54)]

In stark contrast, the accused products do not recess or shield their return electrodes. Instead, the electrodes are large exposed areas adjacent to the electrode terminal that consistently contact body tissue during normal use. [A15360 (963:15-966:10); A15253 (726:4-727:7); A15406 (1023:17-1024:25); A15408 (1030:15-23 & 1032:7-19); A26838-41; A26844-48; A26819-21; A26824-27; A26829-31; A26835-36; A26858-65] The claimed “not in contact” separation between the return and the patient’s body is a critical part of the patented device, but it is simply irrelevant to the accused devices. As a result, the evidence does not show that any of the accused products perform the surgical procedure without their large, exposed return electrodes making contact with body structures.

The circumstantial evidence in the record also is insufficient to support the jury’s verdict. None of the evidence cited by the court, [A68-69], overcomes the clear and conclusive noninfringement evidence presented by the direct evidence in the videos themselves. Indeed, all of this evidence relates to ArthroCare’s flawed and irrelevant claim construction, namely, whether the return electrode momentarily breaks contact with tissue during the energy application step.

For example, Smith & Nephew product documentation does not support a finding of literal infringement under the court's construction. The court cited a Saphyre sales guide cautioning doctors to avoid contact between tissue adjacent a target site and a heated return electrode. [A23162-209] By advising against contact with a potentially "heated" return electrode, this passage plainly refers to the energy application step and does not address the remainder of the method, such as the positioning steps. Furthermore, a phrase cautioning against contact does not mean that doctors have successfully avoided contact in practice. The direct evidence reveals that the intra-joint confines of these procedures are very small, and the large return electrodes of the accused products are exposed, essentially guaranteeing that the return electrode frequently contacts tissue during use. [A15360 (963:15-966:10); A15253 (726:23-727:7); A15406 (1023:17-1024:25); A15408 (1030:15-23 & 1032:7-19); see also A26838-41; A26844-48; A26819-21; A26824-27; A26829-31; A26835-36]

The court also cited an ElectroBlade presentation instructing doctors to "present the smooth blade surface to the tissue . . . when coagulating" and to "use suction to pull bleeding tissue to the blade for coagulation." [A22649] These statements plainly are limited to the energy application step, as coagulation is performed only during energy application. [See A15401 (1001:21-1003:1); A15407-08 (1027:12-1028:10 and 1029:12-1030:10)] Similarly, the passage in the

Control RF Instructions For Use (IFU) document relates to the energy application step instead of the complete method. The Control RF IFU teaches that the “probe tip” should be “completely surrounded by conductive irrigant during use.”

[A22678] This statement merely explains that conductive irrigant is necessary, [A15406-07 (1023:17-1025:2)], but does not address whether the positioning and energy application steps—i.e., the entire method—are performed without the return electrode making contact.

The court also relied on testimony regarding the structural design of the devices as circumstantial evidence that doctors would use the devices in accordance with the claimed method. Specifically, the court cited testimony that the Saphyre would work even if the return electrode did not contact tissue during the energy application step. [A68; A15210 (555:3-11)] Because the Saphyre also works when the return electrode does contact tissue during the energy application step, [A15356 (949:15-950:12)], the cited testimony fails to prove that doctors do not contact tissue with the return electrode “at all” during the method.

Similarly, the designers’ supposed intent for the return electrode not to contact tissue during operation does not prove infringement. [A68-69 (citing A15358 (957-58))] This testimony pertains to only the energy application step—not to the method as a whole. Moreover, the designers unequivocally testified that, because they expected the devices to contact tissue, they designed the devices to

ensure that this contact would not harm the patient. [A15358 (957:21-958:9); A15360 (963:15-966:10); A15253 (726:23-727:7); A15406 (1023:17-1024:25); A15408 (1030:15-23 & 1032:7-19)]

None of the evidence upon which the court relied to deny Smith & Nephew's motion thus provides substantial evidence of literal infringement under the court's claim construction.¹⁸ No other evidence supports the jury verdict. Although ArthroCare's expert, Dr. Goldberg opined that "as long as the return electrode is not in contact while [the] energy is on, this device infringes," [A15155-57 (422:14-423:5; 427:12-13)], he ignored the court's construction requiring that "the return electrode is not to contact the body at all" during the three claimed steps.

B. Given the Lack of Evidence, ArthroCare Invited the Court and Jury to Disregard the Claim Construction

Faced with this undisputed and irrefutable evidence that the accused products do not infringe the claims, as construed by the court, ArthroCare invited the jury to disregard the claim construction. ArthroCare and its expert told the jury that it could find infringement if the return electrode did not touch tissue at any time "when energy is applied." [A15592-93 (1580:17-1582:7 & 1583:20-1584:7)]

By focusing on only a single moment during one of the three claimed steps and

¹⁸ The lack of substantial evidence of direct infringement prevents Smith & Nephew from being liable for inducement of infringement or contributory infringement. Joy Techs., Inc. v. Flakt, Inc., 6 F.3d 770, 774 (Fed. Cir. 1993).

ignoring the positioning steps entirely, ArthroCare misrepresented the court's claim construction. The court likewise erred in ignoring the claim construction given to the jury and adopting ArthroCare's flawed construction for the post-trial motions. See Hewlett-Packard Co. v. Mustek Sys., Inc., 340 F.3d 1314, 1321 (Fed. Cir. 2003) ("The verdict must be tested by the charge actually given [to the jury]"); Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1313-14 (Fed. Cir. 2003) (reversing district court for allowing the jury to ignore the jury instructions and import additional limitations into the claims).

Accordingly, this Court should make clear that the original claim construction in this case controls and enter judgment that Smith & Nephew does not infringe the asserted claims of the '592 patent and claim 47 of the '536 patent.

V. The Jury Erred in Determining That the '882 Patent's Certificate of Correction is Not Invalid

The validity of the Certificate of Correction¹⁹ is central to the question of infringement because original claim 1 recites at least three electrodes. [A18631]

¹⁹ The clear and convincing standard applies "to challenges to the validity of certificates correcting the language of a claim." Superior, 270 F.3d at 1367. "Whether the APA standards of appellate review supplant the clear and convincing evidentiary standard applicable to validity challenges is a separate question," which this Court has not addressed. Id. Under either standard, this Court should reverse the district court's decision to deny Smith & Nephew's motion for judgment as a matter of law. Smith & Nephew maintains, furthermore, that the validity of the Certificate of Correction is an issue for this Court to review without deference because it turns on the interpretation of the patent's intrinsic evidence, id. at 1373. Cf. Cybor, 138 F.3d at 1455-56.

As ArthroCare's expert admitted, the Saphyre and Control RF do not infringe this claim because each of them has only two electrodes—one active electrode and one return electrode.²⁰ [A5019, A5020, A5022; A15428 (1109:23-1110:20, 1111:10-1112:4) (ArthroCare's expert's testimony)] Thus, this supposed "minor" correction made by the Certificate is actually a material change that determines the outcome of this case. Instead of resorting to reissue, which the PTO rules and statute proscribe for the correction of material defects in patents, ArthroCare used the abbreviated certificate of correction process that short-circuits substantive reissue correction procedures. Because the change ArthroCare made is not one clearly indicated by the intrinsic evidence, the Certificate of Correction is invalid, and the judgment must be reversed.

Claim 1 appears below with the Certificate of Correction's additions underlined and deletions stricken:

1. A method for applying energy to a target site on a patient body structure comprising:
providing an electrode terminal [1] and a return electrode [2]
electrically coupled to a high frequency voltage source;
positioning the ~~active~~ electrode [3] terminal in close proximity to the target site in the presence of an electrically conducting ~~terminal~~ fluid;
and
applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode

²⁰ ArthroCare did not assert the '882 patent against the ElectroBlade.

terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

[Compare A18637 with A18631 (24:6-18)]

Originally-issued claim 1 recites at least three electrodes: electrode terminal [1], return electrode [2], and active electrode [3]. [A18631] The corrected claim recites only two electrodes: electrode terminal [1] and return electrode [2]. [A18637] Because “active electrode [3]” became “electrode terminal,” the corrected claim recites fewer electrodes, which broadens its scope. [Compare A18637 with A18631] Even ArthroCare’s expert admitted that the corrected claim is broader than the originally-issued claim. [See A15428 (1109:20-1111:9)]

As a threshold matter, the PTO correctly determined that originally-issued claim 1 has an error. Specifically, in the “positioning the active electrode in close proximity . . .” step, originally-issued claim 1 introduces a term, “the active electrode,” that has no antecedent basis. See In re Altenpohl, 500 F.2d 1151, 1156 (CCPA 1974) (“Lack of antecedent basis in a claim could render it invalid under 35 U.S.C. 112, second paragraph . . .”).

The Certificate of Correction is invalid because the way it corrects this antecedent basis problem is not unambiguously required by the intrinsic evidence. “[A] broadening correction of a clerical or typographical error [is] allowed only where it is clearly evident from the specification, drawings, and prosecution history how the error should appropriately be corrected.” Superior, 270 F.3d at 1373; see

also 35 U.S.C. § 255 (1994). Notably, in this inquiry, one should consider only the specification, drawings, and prosecution history (i.e., the intrinsic evidence).²¹

In its zeal to ensnare its competitors' products, ArthroCare avoided the most natural correction that would solve the antecedent basis problem in original claim 1—namely, change “the active electrode” to “an active electrode.” See Robert C. Faber, Landis on Mechanics of Patent Claim Drafting § 3:11 (5th ed. 2003) (“The first time an element or part is mentioned, it should not be preceded by a definite article (‘the’) or by ‘said.’ Instead, the indefinite article (‘a’ or ‘an’) should be used”). In this way, the claim would recite an active electrode, an electrode terminal, and a return electrode. This type of correction is the only one that does not require a further correction to a dependent claim. Claim 53, for example, depends indirectly from claim 1 and recites “translating the distal surface of the active electrode” [A18633 (emphasis added)] Indeed, ArthroCare’s Certificate of Correction creates an antecedent basis problem for claim 53 with respect to its recitation of “the active electrode,” [A18633], and thus renders it invalid.

The prosecution history indicates that ArthroCare intentionally sought claims reciting both an active electrode and an electrode terminal. In an

²¹ The district court cited the prosecuting attorney’s testimony to support the jury’s supposed finding that the intrinsic evidence unambiguously indicates that the mistake should be corrected as set forth in the Certificate of Correction. [A29-30] Because this testimony is irrelevant, the court and the jury erred in relying on it.

amendment, ArthroCare replaced several occurrences of “active electrode” with “electrode terminal” in the claims, but did not eliminate all occurrences of “active electrode.” [A21471-482] Specifically, it left “active electrode” in pending claims 23, 52, 54, and 56 (issued claims 1, 26, 32, and 34), and continued to use the term in newly-added claim 102 (issued claim 53). [A21472, 21475-477, A21481] After this amendment, some independent claims recite one active electrode and a return electrode (e.g., pending claim 48/issued claim 28), whereas other claims recite two active electrodes and a return electrode (e.g., pending claims 23 and 52). The different types of claims correspond to the different embodiments disclosed in the ’882 patent: embodiments having one active electrode (Figs. 21-22 & 24) and embodiments having at least two active electrodes (Figs. 2-15 & 23). [A18604-611; A18629 (20:19-48) (stating that “the present invention comprising a single active electrode 58”); A18627 (16:41-43) (“[T]he electrically isolated electrode terminals 58 are spaced-apart over an electrode array surface 82.”)]

Therefore, the ’882 patent’s written description, figures, other claims, and prosecution history together tell the public that an appropriate way to correct the antecedent basis mistake in originally-issued claim 1 is simply to change “the active electrode” to “an active electrode.” In light of this teaching, no reasonable jury could have found that the PTO correctly determined that the change imposed by the Certificate of Correction is the only possible appropriate correction. See

Superior, 270 F.3d at 1373 (requiring it to be “clearly evident from the specification, drawings, and prosecution history how the error should be appropriately corrected”). Indeed, the Certificate of Correction is not an appropriate correction at all because it renders claim 53 invalid. Accordingly, Smith & Nephew is entitled to judgment as a matter of law of noninfringement of the '882 patent. See Akami Techs., Inc. v. Cable & Wireless Internet Servs., Inc., 344 F.3d 1186, 1192 (Fed. Cir. 2003).

CONCLUSION

For the reasons stated above, this Court should reverse the dismissal of Smith & Nephew's antitrust counterclaims, reverse the denial of judgment as a matter of law on all accounts, and vacate the permanent injunction.

Dated: September 29, 2004

Respectfully submitted,

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ADDENDUM

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

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MEMORANDUM OPINION

Dated: March 10, 2004
Wilmington, Delaware


ROBINSON, Chief Judge

I. INTRODUCTION

On July 25, 2001, plaintiff Arthrocare Corporation ("Arthrocare") filed this action against defendant Smith & Nephew, Inc. ("Smith & Nephew") alleging willful direct, contributory, and inducing infringement of certain claims of U.S. Patent Nos. 5,697,536 (the "'536 patent"), 5,697,882 (the "'882 patent") and 6,224,592 (the "'592 patent"). (D.I. 1) Smith & Nephew answered the complaint on September 13, 2001 denying the infringement allegations and asserting five affirmative defenses including noninfringement, invalidity, misuse, unenforceability based upon inequitable conduct, and unclean hands. (Id.) Smith & Nephew also asserted counterclaims for a declaratory judgment that the patents in suit are invalid and not infringed by any act of Smith & Nephew and that the '592 patent is unenforceable due to inequitable conduct. (D.I. 10) On September 26, 2001, Arthrocare denied Smith & Nephew's counterclaims. (D.I. 20) With the court's permission, Smith & Nephew amended their answer on November 27, 2002 to add counterclaims for antitrust violations under 15 U.S.C. § 1 of the Sherman Act. (D.I. 219)

ArthroCare is organized under the laws of the State of Delaware with its principal place of business in California. (D.I. 1 at ¶2) Smith & Nephew is also organized under the laws of State of Delaware with its principal place of business in

Massachusetts. (Id. at 13) The court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201(a).

The court separated the issues raised by the parties into two phases, the first phase to include the issues of infringement, validity, and inequitable conduct and the second phase to include the issues of damages, willfulness, and antitrust counterclaims. From April 30, 2003 through May 9, 2003, the parties tried the issues of infringement and invalidity before a jury. The court ruled on May 12, 2003 that the parties could submit their inequitable conduct cases on the briefs limited to the record created at trial. (See D.I. 418 at 1071-02) Currently before the court are the parties' post-trial motions on the issues of infringement, invalidity, and inequitable conduct.¹ (D.I. 424, 427, 432, 437, 455, 458)

¹Smith & Nephew challenges every decision made by the jury in rendering its verdict and numerous evidentiary decisions rendered by the court during the trial.

Smith & Nephew filed a motion to modify the protective order to permit key Smith & Nephew business personnel to view specific terms of Arthrocare's settlement agreement with Ethicon in an attempt to facilitate settlement discussions between the parties. (D.I. 432) Because there are no active settlement discussions currently ongoing, the court denies this motion as moot.

Smith & Nephew also filed a motion for judgment as a matter of law on the issues of (1) infringement under the doctrine of equivalents; (2) infringement of claim 54 of the '882 patent by non-suction models of the Saphyre probe; and (3) direct infringement of the '592 and '882 patents. (See D.I. 459 at 5, 6, and 19) None of these issues were presented to the jury. Likewise, neither the jury instructions nor the special verdict form asked the jury to decide these issues. Accordingly, the court finds that judgment as a matter of law is improper under the federal rules and will not entertain these motions.

II. BACKGROUND

A. Electrosurgery In General

The patents in suit generally relate to electrosurgery and to surgical devices and methods that employ high frequency voltage to cut and ablate tissue. These devices are of either a monopolar or a bipolar nature. A monopolar device, as the name suggests, consists of only a single electrode. It directs an electric current from the exposed or active electrode through a patient's body to a return electrode externally attached to the patient's body. In contrast, a bipolar device consists of two electrodes. An active electrode in contact with the patient's tissue transmits an electric current through the patient's tissue to a return electrode also in contact with the patient's tissue. When using either type of device, the target region must be treated with isotonic saline to maintain an isotonic environment around the tissue and to keep the area in clear view.

Electrosurgical techniques are advantageous because they reduce patient bleeding and the trauma associated with operations involving cutting. At the same time, a diverse range of risks may be implicated. With monopolar devices, electric current may flow in undefined paths through a patient's body. Also, high voltages typically must be applied to generate a current suitable for cutting or ablation using either monopolar or bipolar

devices. Such high voltage may damage or destroy surrounding tissue.

B. The Patents In Suit

The patents in suit involve improvements over the monopolar and bipolar devices of the prior art. Specifically, the '536 patent claims an electrosurgical system comprising an electrosurgical probe, a return electrode, and a fluid delivery element. The '592 and '882 patents, in turn, claim methods of using the system disclosed in the '536 patent to apply electrical energy adjacent to the target tissue without submerging the target tissue in an electrically conducting irrigant. Each patent will be considered in further detail as relevant to the parties' post-trial motions.

1. The '536 Patent

The '536 patent, entitled "System and Method for Electrosurgical Cutting and Ablation," was issued on December 16, 1997 with Philip E. Eggers and Hira V. Thapliyal as inventors. It was originally filed on November 18, 1996. The '536 patent traces priority to the now abandoned U.S. Application No. 817,575. It was granted with sixty-four claims on December 16, 1997. On December 23, 1999, a third party filed a request for an ex parte reexamination based solely upon prior art. The United States Patent and Trademark Office ("PTO") granted this request

and, after reexam, issued a "Notice of Intent to Issue an Ex Parte Reexamination Certificate" as to all original claims.

Claims 46, 47, and 56 are presently asserted and are apparatus type claims. Claims 46 and 56 depend from claim 45. Claim 47 depends from claim 46. These claims read as follows:

45. An electrosurgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:
 - a high frequency power supply;
 - an electrosurgical probe comprising a shaft having a proximal end and a distal end, and a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply;
 - a return electrode electrically coupled to the electrosurgical power supply; and
 - an electrically conducting fluid supply for directing electrically conducting fluid to the target site such that the electrically conducting fluid generates a current flow path between the return electrode and the electrode terminal.
46. An electrosurgical system as in claim 45, wherein the return electrode forms a portion of the shaft of the electrosurgical probe.
47. An electrosurgical system as in claim 46 further including an insulating member circumscribing the return electrode, the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and the patient's tissue.
56. The electrosurgical system of claim 45 wherein the target site is selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.

('536 patent, col. 18 at ll. 13-36; col. 19 at ll. 11-15)

The court construed disputed terms of the '536 patent to ascertain both their meaning and scope. (D.I. 353) The most significant constructions for the purposes of resolving the parties' post-trial motions are as follows:

1. The term "electrosurgical system" shall be given its "ordinary definition" and construed to mean "an assemblage or combination of things or parts forming a unitary whole."
2. The term "return electrode" shall be construed to mean "an electrode having a larger area of contact than an active electrode, thus affording a lower current density."
3. The term "connector" shall be construed to mean "a structure that electrically links the electrode terminal to the high frequency power supply."
4. The phrases "spacing a return electrode away from the body structure" and "the return electrode is not in contact with the body structure" shall be construed to mean that the return electrode is not to contact the body at all during the performance of the claimed method.²
5. The term "electrically conducting fluid" and "electrically conductive fluid" shall be construed to mean "any fluid that facilitates the passage of electrical current."

²The court supplemented this construction in its jury instructions with the following addition: "The claimed method does not contain any time limitations. Thus, the claimed method is performed when each of the three steps has been completed." (D.I. 418 at 1718)

2. The '882 Patent

The '882 patent, entitled "System and Method for Electrosurgical Cutting and Ablation," was issued on December 16, 1997 with Philip E. Eggers and Hira V. Thapliyal as inventors. It was originally filed on November 22, 1995 and traces priority to the same original application as the '536 patent, namely U.S. Application No. 817,575. The '882 patent was granted with fifty-six claims on December 16, 1997. Claims 13, 17, and 54 are presently asserted. All are method type claims. Claims 13 and 17 depend from claim 1 and claim 54 depends from both claim 1 and claim 28. These claims recite:

1. A method for applying energy to a target site on a patient body structure comprising:
providing an electrode terminal and a return electrode, electrically coupled to a high frequency voltage source;
positioning the active electrode in close proximity to the target site in the presence of an electrically conducting fluid; and
applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.
13. The method of claim 1 wherein at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.
17. The method of claim 1 wherein the high frequency voltage is at least 200 volts peak to peak.
28. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source; positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to impart sufficient energy into the target site to ablate the body structure without causing substantial tissue necrosis below the surface of the body structure underlying the ablated body structure.

54. The method of claims 1 and 28 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.

('882 patent, col. 24 at ll. 5-18; 54-56, 64-65; col. 25 at ll. 38-51; col. 28 at ll. 9-10)

Pursuant to multiple certificates of correction granted after the '882 patent originally issued, the language recited in several claims was corrected. Of interest to the parties' post-trial motions, claim 1 was corrected on April 7, 1998. Claim 54 was corrected on May 2, 1998. For sake of clarity, the corrected language is shown below in bold with the original language in parentheses.

1. A method for applying energy to a target site on a patient body structure comprising:
providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;
positioning the [active] electrode terminal in close proximity to the target site in the presence of an electrically conducting [terminal] fluid; and
applying a high frequency voltage between the electrode terminal and the return electrode,

the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

54. The method of claims [1 and 28] 23 or 48 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.

('882 patent, Certificates of Correction dated August 25, 1998, April 7, 1998, and May 2, 2001) (emphasis added)

3. The '592 Patent

The '592 patent, entitled "Systems and Methods for Electrosurgical Tissue Treatment in Conductive Fluid," was issued on May 1, 2001 with Philip E. Eggers and Hira V. Thapliyal as inventors. It was originally filed on July 27, 1998 and traces priority to the '882 patent. Specifically, the '592 patent is a division of U.S. Patent No. 5,871,469, which is a division of the '882 patent. The '592 patent was granted with forty-three claims on May 1, 2001. Claims 1, 3, 4, 11, 21, 23, 26, 27, 32, and 42 are presently asserted and are all method type claims. Claims 3, 4, 11, and 21 depend from claim 1. Claim 26, 27, 32, and 42 depend from claim 23. These claims read as follows:

1. A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising:
positioning an electrode terminal into at least close proximity with the target site in the presence of an electrically conductive fluid;
positioning a return electrode within the electrically conductive fluid such that the return electrode is not in contact with the body structure to generate

a current flow path between the electrode terminal and the return electrode; and
applying a high frequency voltage difference between the electrode terminal and the return electrode such that an electrical current flows from the electrode terminal, through the region of the target site, and to the return electrode through the current flow path.

3. The method of claim 1 further comprising immersing the target site within a volume of the electrically conductive fluid and positioning the return electrode within the volume of electrically conductive fluid to generate the current flow path between the electrode terminal and the return electrode.
4. The method of claim 1 further comprising delivering the electrically conductive fluid to the target site.
11. The method of claim 1 wherein the electrically conductive fluid comprises isotonic saline.
21. The method of claim 1 wherein the voltage is in the range from 500 to 1400 volts peak to peak.
23. A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising:
contacting an active electrode with the body structure in the presence of an electrically conductive fluid;
spacing a return electrode away from the body structure in the presence of the electrically conductive fluid; and
applying a high frequency voltage difference between the active electrode and the return electrode such that an electrical current flows from the active electrode, through the electrically conductive fluid, and to the return electrode.
26. The method of claim 23 further comprising immersing the target site within a volume of the electrically conductive fluid and positioning the return electrode within the volume of electrically conductive fluid to generate a current flow path

between the active electrode and the return electrode.

27. The method of claim 23 further comprising delivering the electrically conductive fluid to the target site.
32. The method of claim 23 wherein the electrically conductive fluid comprises isotonic saline.
42. The method of claim 23 wherein the voltage is in the range from 500 to 1400 volts peak to peak.

('592 patent, col. 24 at ll. 6-21; 36-32; 64-65; col. 25 at ll. 36-37, 43-54, 61-67; col. 26 at ll. 20-21, 59-60)

The court construed disputed terms of the '592 patent to ascertain both their meaning and scope. (D.I. 353) The most significant constructions for the purposes of resolving the parties' post-trial motions are as follows:

1. The phrase "spacing a return electrode away from the body structure" and "the return electrode is not in contact with the body structure" means that the return electrode is not to contact the body at all during the performance of the claimed method.³
2. The term "electrically conducting fluid" and "electrically conductive fluid" shall be construed to mean "any fluid that facilitates the passage of electrical current."
3. The term "return electrode" shall be construed to mean "an electrode having a larger area of contact than an active electrode, thus affording a lower current density."

³The court supplemented this construction in its jury instructions. The court added the following: "The claimed method does not contain any time limitations. Thus, the claimed method is performed when each of the three steps has been completed." (D.I. 418 at 1718)

(D.I. 353)

C. The Accused Products

Smith & Nephew presently manufactures and sells the Saphyre bipolar ablation probe ("Saphyre") and the ElectroBlade Resector ("ElectroBlade") for use in arthroscopic procedures. These products entered the market in 2002. It also previously manufactured and sold the Dyonics Control RF System ("Control RF") for use in arthroscopic procedures, but discontinued this product from the market in early 2002. (D.I. 436 at 3)

The Saphyre product consists of a stainless steel shaft with a plastic handle and a single large area active electrode at the far or "distal" end of the "shaft." (D.I. 400 at 3) The inner and outer surfaces of the Saphyre shaft are covered with an insulating coating, except at the distal tip where the active electrode is located. (Id.) A single return electrode clip is attached on top of this insulated shaft. (Id.) The return electrode and insulated shaft are covered with another insulating layer, except for a window located over the return electrode clip near the distal end of the shaft. (Id.) The Saphyre probe is connected to the Smith & Nephew Vulcan Generator. (Id. at 4)

The ElectroBlade probe consists of a stainless steel inner tube (i.e., inner blade) and a hollow stainless steel shaft (i.e., outer blade). (Id.) The inner blade slides into the shaft hollow and includes an opening near its distal end. The

inner blade rotates within the shaft when connected to a motor drive unit. (Id.) When it passes the edge of the opening in the shaft during rotation, a shearing action results. (Id. at 5) This shearing action serves to resect, or cut, target tissue. In addition to resecting tissue, the inner blade also acts as the active electrode when coagulation power is applied to the probe. (Id.) The return electrode is another hollow, stainless steel tube that runs from a point close to the opening in the shaft to a point in the handle. (Id.) The return electrode is covered with an insulating layer, except for an exposed section near the distal end of the shaft. The ElectroBlade probe does not contain a fluid delivery system. Instead, a separate instrument delivers fluid to the target tissue during an arthroscopic procedure. (Id. at 4) The ElectroBlade probe is connected to the Valleylab Force FX Generator. (Id. at 5)

Before being discontinued, the Control RF probe consisted of a stainless steel shaft in a plastic handle with a single active electrode at the far end. (Id. at 6) A return electrode was located near the active electrode at the far end of the shaft. The majority of the shaft was covered with an insulating material, except in the region of the active and return electrodes. (Id.) The Control RF probe did not contain a fluid delivery system; instead, a separate instrument pumped fluid during an arthroscopic surgery to the target tissue. (Id.) The

Control RF probe was connected to a Valleylab Force FX Generator via a Dyonics Control RF Generator Adaptor. (Id.)

D. The Alleged Prior Art

Throughout the course of the trial, Smith & Nephew introduced numerous documents in an attempt to establish that the patents in suit were invalid in light of prior art references.⁴ These references include four patents and two journal articles as follows: (1) U.S. Patent No. 4,116,198 (the "'198 patent"); (2) U.S. Patent No. 4,381,007 (the "'007 patent"); (3) U.S. Patent No. 4,674,499 (the "'499 patent"); (4) U.S. Patent No. 5,122,138 (the "'138 patent"); (5) "Vaporization of Atherosclerotic Plaques by Spark Erosion," 5 Journal of the American College of Cardiology, No. 6 at 1382-6 (1985) written by Cornelis J. Slager, et. al. (the "Slager article"); and (6) "Uber ein Instrument zur leckstromfreien transurethralen Resektion," (translated as "An Instrument for Transurethral Resection Without Leakage of Currents"), 24 Acta Medico Technica, No. 4 at 129-134 (1976) written by Von E. Elsasser and Eberhard. Roos (the "Elsasser/Roos article"). The '007 and '499 patents were cited to the PTO during the prosecution of the '536 and '882 patents. (See '536 patent cover; '882 patent cover) The Elsasser/Roos article was also cited during the prosecution of the '536 patent, and the

⁴The parties did not dispute that the documents introduced at trial by Smith & Nephew qualified as prior art in that they were available prior to the filing dates of the patents in suit.

'198 patent was cited during the reexamination of the '536 patent. (See '198 patent cover; '198 patent reexamination certificate)

The '198 patent, entitled "Electro-Surgical Device," is the most contentious item of prior art raised in the litigation at bar. Eberhard Roos is named as the sole inventor on this patent. In general, it relates to a bipolar electrosurgical device that may be passed through an endoscope. The device consists of a treatment electrode, a neutral electrode, a cable means to connect the treatment electrode to one pole of a high-frequency generator, another means for connecting the neutral electrode to the other pole of the high-frequency generator, and a channel for directing washing liquid to the treatment site. ('198 patent, col. 7 at ll. 45-61) The '198 invention is particularly directed toward electrosurgical operations on the filled bladder. (Id., col. 1 at ll. 18-21) Claim 1 of this patent recites:

1. In combination, an endoscope having an endoscope body of substantially tubular shape, an electrosurgical device comprising a treatment electrode projecting at one end from said endoscope body and a neutral electrode arranged adjacent said treatment electrode, insulated cable means for connecting said treatment electrode to one pole of a high-frequency generator, and means for connecting said neutral electrode to the other pole of a high-frequency generator, said endoscope body having an insulating projection extending over a portion of the periphery of said endoscope body at said one end and having a front edge, said neutral electrode being located within said endoscope body and spaced a distinct distance inwardly from said front edge, a space being

formed between said treatment electrode and said neutral electrode which is adapted to be filled with liquid to provide electrical conductance between said electrodes.

(Id., col. 7 at ll. 45-62) (emphasis added)

The '007 patent is entitled, "Multipolar Corneal-Shaping Electrode with Flexible Removable Skirt," and names James D. Doss as the sole inventor. This patent is directed toward a multipolar probe that employs radiofrequency electrical current to heat and thereby induce reshaping of the cornea in mammals. ('007 patent, col. 1 at ll. 10-13) The probe employs a plurality of electrode means that may be connected to the terminal of a radio-frequency source. (Id., col. 6 at ll. 60-61)

The '499 patent is entitled, "Coaxial Bipolar Probe," and names David S.C. Pao as the sole inventor. It discloses an electrosurgical bipolar electrode probe for use in ophthalmic, electrocautery, and electrocoagulation operations. ('499 patent, col. 1 at ll. 15-18)

The '138 patent is entitled, "Tissue Vaporizing Accessory and Method for an Endoscope," and names Kim H. Manwaring as the sole inventor. This patent is directed toward radio frequency energized endoscopic tissue dissection, vaporization, and coagulation devices designed for use in conjunction with an endoscope. ('138 patent, col. 1 at ll. 7-9; col. 2 at ll. 5-8) These devices may utilize a monopolar RF generator.

The Elsasser/Roos article essentially describes using one of the bipolar electrosurgery devices described in the '198 patent in thirty-two surgeries. In the summary section, this article states that "[t]he high-frequency current . . . flows directly from the active cutting electrode, through the tissue to be cut and the irrigation liquid, to the annular neutral electrode at the proximal end of the resectoscope shaft." (DTX 59-B at 7) (emphasis added) The Slager article describes the in vitro vaporization of fibrous and lipid plaques from segments of atherosclerotic human aortas using an electrical spark generator. (DTX 65)

E. The Arthrocare Corp. v. Ethicon, Inc. Decision

Arthrocare filed suit against Ethicon, Inc., Mitek Surgical Products, Inc., and Gynecare, Inc. in the Northern District of California on February 13, 1998, alleging infringement of eight claims in four patents. (Arthrocare Corp. v. Ethicon, Inc., No. C-98-0609 WHO (N.D. Cal. Dec. 1, 1998); D.I. 321, ex. A at 1) The claims at issue included: (1) claims 40 and 44 of U.S. Patent No. 5,697,909 (the "'909 patent"); (2) claim 45 of the '536 patent; (3) claim 101 of U.S. Patent No. 5,697, 281 (the "'281 patent"); and (4) claims 1, 26, 28, and 32 of the '882 patent. (Id. at 2) The case was assigned to Senior Judge William H. Orrick.

On March 10, 1998, Arthrocare moved for a preliminary injunction against Ethicon and Mitek to enjoin the two from making, using, importing, selling, or offering for sale an electrosurgery system marketed and sold under the VAPR System name. (Id.) Judge Orrick issued a memorandum decision on December 1, 1998 denying Arthrocare's preliminary injunction motion. (Id. at 33) Judge Orrick found substantial questions as to whether: (1) claims 40 and 44 of the '909 patent and claims 26 and 28 of the '882 patent are invalid for obviousness in light of the '198 patent and Elsasser/Roos article; (2) claim 45 of the '536 patent and claim 101 of the '281 patent are invalid for anticipation and obviousness in light of the '198 patent and Elsasser/Roos article; and (3) claims 1 and 32 of the '882 patent are invalid for lack of enablement. (Id.) The parties settled the litigation in June 1999 prior to trial.

F. Procedural History

In March 2003, the parties filed multiple motions for partial summary judgment. The court heard oral argument regarding these motions on April 1, 2003 and issued a memorandum opinion and order on April 9, 2003. (D.I. 352) The court denied Arthrocare's motions for partial summary judgment of infringement of the asserted claims of the '882 patent and claim 1 of the '592 patent, denied Smith & Nephew's motion for summary judgment of noninfringement of the asserted claims of the '882, '592, and

'536 patents, denied Arthrocare's motion for partial summary judgment that the patents in suit are not invalid due to obviousness based on an on-sale bar or public use, denied Smith & Nephew's motion for summary judgment of invalidity based upon prior art, and denied Smith & Nephew's motion for partial summary judgment of nonenablement, indefiniteness, and lack of written description. (Id.)

During the April 1, 2003 oral argument, the court also heard the parties' positions with respect to the disputed claim language of the patents in suit in accordance with Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996). The court issued a claim construction memorandum order on April 9, 2003. (D.I. 353)

G. The Trial

On April 30, 2003 through May 12, 2003, the parties tried their claims to a jury. The jury found by a preponderance of the evidence that Smith & Nephew directly infringed, induced infringement, and contributed to the infringement of claims 46, 47, and 56 of the '536 patent with its Saphyre, ElectroBlade, and Control RF products. (D.I. 405) The jury also found by clear and convincing evidence that the certificate of correction for claim 1 of the '882 patent was not invalid and by a preponderance of the evidence that Smith & Nephew induced infringement and contributed to the infringement of claims 13, 17, and 54 of the

'882 patent with its Saphyre, Saphyre with Suction, and Control RF products. (Id.) In addition, the jury found by a preponderance of the evidence that Smith & Nephew induced infringement and contributed to the infringement of claims 1, 3, 4, 11, 21, 23, 26, 27, 32, and 42 of the '592 patent with its Saphyre, ElectroBlade, and Control RF products.⁵ (Id.) The jury further found that Smith & Nephew did not prove by clear and convincing evidence that the patents in suit are invalid due to anticipation or that claims 13, 17, and 54 of the '882 patent are invalid for lack of enablement. (Id.) The court entered final judgment on June 20, 2003 based upon the jury's verdict. (D.I. 452)

III. STANDARD OF REVIEW

A. Motion for Judgment as a Matter of Law

To prevail on a renewed motion for judgment as a matter of law following a jury trial under Federal Rule of Civil Procedure 50(b), the moving party "must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusions implied [by] the jury's verdict cannot in law be supported by those findings." Pannu v. Iolab Corp., 155 F.3d 1344, 1348 (Fed. Cir. 1998)

⁵The jury was not asked to decide whether Smith & Nephew contributed to the infringement or induced the infringement of claims 21 and 42 of the '592 patent with its Saphyre or ElectroBlade products.

(quoting Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893 (Fed. Cir. 1984)). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be acceptable by a reasonable mind as adequate to support the finding under review." Perkin-Elmer Corp., 732 F.2d at 893. In assessing the sufficiency of the evidence, the court must give the non-moving party, "as [the] verdict winner, the benefit of all logical inferences that could be drawn from the evidence presented, resolve all conflicts in the evidence in his favor, and in general, view the record in the light most favorable to him." Williamson v. Consol. Rail Corp., 926 F.2d 1344, 1348 (3d Cir. 1991); Perkin-Elmer Corp., 732 F.2d at 893. The court may not determine the credibility of the witnesses nor "substitute its choice for that of the jury between conflicting elements of the evidence." Id. In summary, the court must determine whether the evidence reasonably supports the jury's verdict. See Dawn Equip. Co. v. Kentucky Farms Inc., 140 F.3d 1009, 1014 (Fed. Cir. 1998).

B. Motion for a New Trial

The decision to grant or deny a new trial is within the sound discretion of the trial court and, unlike the standard for determining judgment as a matter of law, the court need not view the evidence in the light most favorable to the verdict winner. See Allied Chem. Corp. v. Darflon, Inc., 449 U.S. 33, 36 (1980).

Federal Rule of Civil Procedure 59(a) provides, in pertinent part:

A new trial may be granted to all or any of the parties and on all or part of the issues in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States.

New trial are commonly granted in the following situations: (1) where the jury's verdict is against the clear weight of the evidence, and a new trial must be granted to prevent a miscarriage of justice; (2) where newly-discovered evidence surfaces that would likely alter the outcome of the trial; (3) where improper conduct by an attorney or the court unfairly influenced the verdict; or (4) where the jury's verdict was facially inconsistent. See Zarow-Smith v. N.J. Transit Rail Operations, 953 F. Supp. 581, 584 (D. N.J. 1997) (citations omitted). The court, however, must proceed cautiously and not substitute its own judgment of the facts and assessment of the witnesses' credibility for the jury's independent evaluation. Nevertheless,

[w]here a trial is long and complicated and deals with a subject matter not lying within the ordinary knowledge of jurors a verdict should be scrutinized more closely by the trial judge than is necessary where the litigation deals with material which is familiar and simple, the evidence relating to ordinary commercial practices. An example of subject matter unfamiliar to a layman would be a case requiring a jury to pass upon the nature of an alleged newly discovered organic compound in an infringement action.

Lind v. Schenley Indus. Inc., 278 F.2d 79, 90-91 (3d Cir. 1960).

IV. DISCUSSION

A. Smith & Nephew's Renewed Motion for Judgment as a Matter of Law, or in the Alternative a New Trial, on Direct Infringement Grounds⁶

1. The Legal Standard for Direct Infringement

A patent is directly infringed when a person "without authority makes, uses or sells any patented invention, within the United States . . . during the term of the patent." 35 U.S.C. § 271(a) (2002). A court should employ a two-step analysis in making a direct infringement determination. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). First, the court must construe the asserted claims to ascertain their meaning and scope. See id. Construction of the claims is a question of law subject to de novo review. See Cybor Corp. v. FAS Techs., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc). The trier of fact must then compare the properly construed claims with the accused infringing product. See id. This second step is a question of fact. See Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998). Direct infringement occurs where each limitation of

⁶When motioning the court for a new trial under Fed. R. Civ. P. 59, Smith & Nephew appears to also move for a new trial under Fed. R. Civ. P. 50(b). Smith & Nephew premises this motion on the same grounds raised in its motion for judgment as a matter of law under Fed. R. Civ. P. 50(b). (See D.I. 456 at 33-34). The court, therefore, shall consider its Rule 50(b) motion for judgment as a matter of law as including an alternative motion for a new trial.

at least one claim of the patent is found exactly in the alleged infringer's product. See Panduit Corp. v. Dennison Mfg. Co., 836 F.2d 1329, 1330 n. 1 (Fed. Cir. 1987). The patent owner has the burden of proving direct infringement and must meet its burden by a preponderance of the evidence. See SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted).

2. The '536 Patent

Smith & Nephew renews its motion for judgment as a matter of law that its accused products cannot directly infringe independent claim 45 or dependent claims 46, 47, or 56 of the '536 patent because the probes covered by the '536 patent must deliver fluid to the target site in light of the court's claim construction for the term "electrosurgical system." Smith & Nephew asserts that the probes used in its Saphyre, Control RF, and ElectroBlade products do not introduce such a fluid supply, even though they are used in the presence of electrically conducting fluid. To this end, Smith & Nephew explains that fluid is introduced to the target site by a separate piece of medical equipment like an IV bag or an Intelijet pump and that the separate equipment is not part of the "electrosurgical system." (D.I. 415 at 976, 1014) Smith & Nephew alleges that Arthrocare's expert, Dr. Nahum Goldberg, improperly ignored the requirement that an electrically conducting fluid supply be part

of the claimed system in his testimony at trial. (See D.I. 411 at 398-99) Accordingly, Smith & Nephew maintains that its products fall outside the scope of the asserted claims in the '536 patent.

The court disagrees. A jury reasonably may have discounted all testimony presented by Smith & Nephew with respect to direct infringement of the '536 patent after finding Smith & Nephew's use of the term "electrosurgical system" inconsistent with the court's claim construction. The court construed this term to mean "an assemblage or combination of things or parts forming a unitary whole." The court did not require that all elements physically interconnect as implied by Smith & Nephew. Following the court's construction, the jury likely understood that fluid may be delivered from any source (e.g., the probe itself, an IV bag, or an Intelijet pump) and still permit formation of an "electrosurgical system."

Additionally, there is ample evidence in the record upon which a jury reasonably could have concluded that the accused products meet all limitations of the asserted claims. Dr. Goldberg testified that the accused devices will only function in the presence of electrically conducting fluid. (See id. at 398-99, 405, 412) Smith & Nephew's own expert, Dr. Kenneth Taylor, also testified that the accused devices require, and will not work without, electrically conducting fluid. (See D.I. 416 at

1453-54) Dr. Taylor likewise admitted that a probe is not required to deliver fluid for the probe and fluid supply to be considered an "electrosurgical system." (See id. at 1413-16) Moreover, Dr. Taylor explained the components described in the Slager reference comprised an electrosurgical system, even though fluid was not delivered through the probe. (See id. at 1414)

Besides direct witness testimony, the jury viewed multiple video clips of the accused products in operation during "normal procedure." (See PX 105, DTX 315, DTX 316, DTX 897) In all clips, the target sites were submerged under saline fluid. (Id.) The jury further saw product literature from Smith & Nephew, namely the ElectroBlade "Instruction for Use" guide, which described the use of the ElectroBlade in conjunction with the Intelijet pump and referred to this assembly as the "Recommended System Configuration." (PX 189 at 3) On the basis of this evidence, a reasonable jury could conclude that the Saphyre, Control RF, and ElectroBlade probes form an "electrosurgical system" as required by the '536 claims and, as such, infringe the '536 patent. Accordingly, the court denies Smith & Nephew's motion for judgment as a matter of law that the '536 patent is not infringed by the accused products.

Concerning a new trial, the verdict is not against the weight of the evidence and no miscarriage of justice will result if the jury's verdict stands. Smith & Nephew did not present

evidence that so overwhelmingly favors its position that the jury clearly erred in finding that the accused products directly infringe the '536 patent. In addition, the court finds that none of the other reasons for granting a new trial, such as the discovery of new evidence or improper attorney conduct, exist under the facts at bar. Thus, the court denies Smith & Nephew's motion for a new trial as to literal infringement of the '536 patent.

B. Smith & Nephew's Renewed Motion for Judgment as a Matter of Law, or in the Alternative a New Trial, Based Upon the Validity of the Certificate of Correction for the '882 Patent

Smith & Nephew argues that its Saphyre, ElectroBlade, and Control RF probes would not directly infringe the '882 patent but for the certificate of correction that broadened the number of electrodes recited in application claim 23, which became patent claim 1, from four electrodes (i.e., an electrode terminal, an active electrode, a return electrode, and an electrically conducting terminal) to two electrodes (i.e., an electrode terminal and a return electrode). In other words, Smith & Nephew does not contest that its Saphyre, Control RF, and ElectroBlade products directly infringe the asserted claims of the '882 patent as corrected by the certificate of correction because its accused probes have only two electrodes as recited by the corrected

claims.⁷ (See D.I. 415 at 1110-1112) Rather, Smith & Nephew argues that the certificate of correction is invalid. In this regard, Smith & Nephew asserts that it was not obtained to correct a mistake, but only to broaden the claims to advance its lawsuit against Ethicon. Additionally, Smith & Nephew argues that, even if the certificate was filed to correct obvious errors, it was not manifest how such corrections should have been made.

The court disagrees. The record is replete with evidence upon which a jury reasonably could have found that the certificate of correction was validly made to correct legitimate errors in the claims.. Congress enabled a patent applicant to correct errors in a patent due to the applicant's mistake in 35 U.S.C. § 255. This section provides:

Whenever a mistake of a clerical or typographical nature, or of minor character, which was not the fault of the Patent and Trademark Office, appears in a patent and a showing has been made that such mistake occurred in good faith, the Director may, upon payment of the required fee, issue a certificate of correction, if the correction does not involve such changes in the patent as would constitute new matter or would require re-examination. Such patent, together with the certificate, shall have the same effect and operation in law on the trial of actions for causes thereafter arising as if the same had been originally issued in such corrected form.

⁷Smith & Nephew contends that its accused products, however, do not infringe the original claims of the '882 patent. (See also D.I. at 1110)

35 U.S.C. § 255 (2000). This section enumerates two specific kinds of applicant error which may be corrected through a certificate of correction: (1) errors of a clerical or typographical nature; and (2) errors of a minor character. The Federal Circuit has noted that the words of § 255 do not preclude broadening corrections. Superior Fireplace Co. v. The Majestic Prods. Co., 270 F.3d 1358, 1371 (Fed. Cir. 2001). However, the Federal Circuit opined that " a broadening correction of a clerical or typographical error [may] be allowed only where it is clearly evident from the specification, drawings, and prosecution history how the error should appropriately be corrected." Id. at 1373. With regard to mistakes of a minor character, the Federal Circuit has interpreted the language of § 255 to exclude mistakes that broaden a claim. Id. at 1374. The Federal Circuit further has held that the clear and convincing standard is applicable to challenges to the validity of a certificate of correction. Id. at 1367.

Applying these principles to the facts at bar, the court notes that Mr. John Raffle, Arthrocare's in-house counsel, filed an amendment on March 25, 1997 prior to the '882 patent grant to change the phrase "active electrode" to "electrode terminal." Mr. Raffle testified that he attempted to make this change for every occurrence of the phrase "active electrode" in the claims. (See D.I. 417 at 1524-26) Mr. Raffle also testified that the

phrase "the active electrode" in uncorrected application claim 23 lacked antecedent basis because the precise words "an active electrode" did not appear earlier in the claim set. (See id. at 1515-16) Based upon this testimony, the jury could have inferred that Mr. Raffle inadvertently overlooked two occurrences of the phrase "active electrode" in his amendment and that reference to "the active electrode" after the phrase "an electrode terminal" was a typographical error. A jury likewise reasonably could have concluded that both the typographical error and the proper way to correct it were evident in light of the prosecution history of the '882 patent. Accordingly, the court denies Smith & Nephew's motion for judgment as a matter of law that the certificate of correction is invalid.

With respect to a new trial, the weight of the evidence does not warrant a new trial to avoid a miscarriage of justice. Arthrocare offered sufficient evidence upon which a jury could have found that the certificate of correction is valid. Hence, the court denies Smith & Nephew's motion for a new trial premised on the invalidity of the certificate of correction for the '882 patent.

C. Smith & Nephew's Renewed Motion for Judgment as a Matter of Law, or in the Alternative a New Trial, on Contributory and Inducing Infringement Grounds

1. The Legal Standard for Contributory Infringement

The doctrine of contributory infringement is codified at 35 U.S.C. § 271(c):

Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

The Federal Circuit has explained that this form of infringement is premised on the idea that a defendant who displays sufficient culpability should be held liable as an infringer, even though he did not technically make, use, or sell a patented invention.

Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990). The Federal Circuit also has noted that "[s]uch liability was under a theory of joint tortfeasance, wherein one who intentionally caused, or aided and abetted, the commission of a tort by another was jointly and severally liable with the primary tortfeasor." Id. Based upon the language of § 271(c), there can be no contributory infringement in the absence of direct infringement. See Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336, 341-42 (1961). In addition,

there can be no contributory infringement without knowledge that the component made or sold was especially adapted for a particular use proscribed by a known patent. See Hewlett-Packard Co., 909 F.2d at 1469. Actual intent to cause or contribute to infringement is not necessary to establish contributory infringement. Id. Instead, "[a] seller of a 'material part' of a patented item may be a contributory infringer if he makes a non-staple article that he knows was 'especially made or especially adapted for use in an infringement of such patent.'" Husky Injection Molding Sys. v. R&D Tool & Eng'g Co., 291 F.3d 780, 784 (Fed. Cir. 2002) (citing 35 U.S.C. § 271(c); Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 219 (1980)).

Furthermore, the "occasional and aberrant use of these products, [even] where they are clearly designed to be used in a system specified in the claims of a patent, does not rise to the level of 'a staple article or commodity of commerce suitable for substantial non-infringing use.'" Preemption Devices v. Minnesota Mining & Mfg. Co., 630 F. Supp. 463, 471 (E.D. Pa. 1985) (citing Dennison Mfg. Co. v. Ben Clements & Sons, Inc., 467 F. Supp. 391, 428 (S.D.N.Y. 1979)).

2. The Legal Standard for Inducing Infringement

Pursuant to 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." As with contributory infringement, direct infringement is a

prerequisite to inducing infringement. Met-Coil Sys. Corp. v. Korner Unlimited, Inc., 803 F.2d 684, 687 (Fed. Cir. 1986). Additionally, the alleged infringer must have knowingly induced infringement. Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 553 (Fed. Cir. 1990) (citing Water Techs. Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988)). The Federal Circuit has stated that "although section 271(b) does not use the word 'knowing, the case law and legislative history uniformly assert such a requirement." Water Techs., 850 F.2d at 668. In this regard, mere knowledge of the acts alleged to constitute inducement is not enough. Manville Sales Corp., 917 F.2d at 553. Rather, the plaintiff has the burden of showing that "the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements." Id.

3. The Direct Infringement Prerequisite for Contributory and Inducing Infringement⁸

Considering the direct infringement prerequisite for the acts of contributory and inducing infringement, Smith & Nephew

⁸Smith & Nephew argues that it is not liable for contributory or inducing infringement because its accused products do not directly infringe the '536 patent. The court shall not consider this argument in the instant analysis because a jury found that Smith & Nephew directly infringed the '536 patent and the court herein denied Smith & Nephew's motion for judgment as a matter of law on direct infringement grounds for this patent. See supra, Section IV, 1, A.

Recall also Smith & Nephew did not argue noninfringement of the '882 patent as corrected by the certificate of correction.

argues that the Saphyre, Control RF, and ElectroBlade probes do not practice the limitations of asserted claims of the '592 patent. Specifically, Smith & Nephew contends that the return electrodes on its products frequently contact target tissue during the performance of the method for applying electrical energy recited in claims 1 and 23 of the '592 patent.⁹ Claim 1 requires "positioning a return electrode . . . such that [it] is not in contact with the body structure," and claim 23 requires "spacing a return electrode away from the body structure." ('592 patent, col. 24 at ll. 13-14; col. 25 at ll. 48) Smith & Nephew alleges that Dr. Goldberg improperly applied a temporal limitation in testifying that the "only way not to infringe this claim with the device is to make sure that the return electrode . . . is always in contact when the energy is on." (D.I. 411 at 421-22) (emphasis added) Smith & Nephew particularly notes that the return electrodes on its products contact tissue while the probe is being positioned before energy is applied (i.e., during the second step enumerated in claims 1 and 23). Smith & Nephew, therefore, advocates that a reasonable jury could not find that

⁹Procedurally, Smith & Nephew raised the issue of direct infringement of the '592 patent in a motion for judgment as a matter of law. As the court previously noted above, this issue was not presented to the jury. See *supra*, Introduction, n. 1. The court, therefore, construes Smith & Nephew's argument in the context of its motion for judgment as a matter of law on both contributory and inducing infringement grounds.

the use of any of its accused products satisfies the return electrode "not in contact/spaced away" limitations given this contact time. (See D.I. 354 at 7)

Viewing the record in a light most favorable to Arthocare as the non-moving party, the court disagrees with Smith & Nephew's argument. The record reflects that there are times when the return electrode is not in contact with target tissue and all of the other claim limitations are performed, thereby supporting the jury verdict of literal infringement. To this end, Smith & Nephew's expert, Dr. Michael Choti, admitted that when the active electrode on the Control RF probe is positioned near the target site and energy is applied, the return electrode does not always contact tissue. (See D.I. 412 at 743-744) Ms. Karen Drucker, the ElectroBlade project manager, and Ms. Kate Knudsens, the Saphyre project manager, similarly acknowledged that video clips of the accused products in operation show times when the return electrodes of the ElectroBlade and Saphyre probes, respectively, were not in contact with tissue while energy was applied. (See D.I. 415 at 1036, 985) Mr. Warren Heim, Smith & Nephew's consultant, also testified that the Control RF probe was designed so that the return electrode would not contact tissue during use. (See D.I. 414 at 957-58) Additionally, Mr. Joe McCreary, the Saphyre marketing manager, testified that the Saphyre can function even if the return electrode is not in contact with

tissue. (See D.I. 412 at 555) Moreover, the Saphyre Sales Guide warns that "care should be taken to prevent tissue contact with the return electrode on the Saphyre probe shaft." (PX 390 at 37)

The ElectroBlade Sales Training CD likewise instructs users to "ensure that the entire tip including the return electrode is immersed in saline, to "present" the active electrode to the tissue, and "to use suction to pull bleeding tissue to the blade for coagulation." (PX 199 at 11, 7) The Control RF

"Instructions for Use" further informs doctors to be sure that the active and return electrodes are "completely surrounded" by electrically conducting fluid during use." (PTX 205 at 1)

Considering the totality of this evidence, a jury reasonably could have found that Smith & Nephew's accused products meet the "not in contact/spaced away" limitations of the asserted claims and thereby directly infringe the '592 patent.

4. Contributory Infringement

Smith & Nephew asserts that its products have "substantial non-infringing uses" such that they were not designed to infringe the asserted claims of the patents in suit. Specifically, Smith & Nephew claims that these non-infringing uses include: (1) operation of the probes to apply energy while the return electrode touches tissue (i.e., noninfringement of the '592 patent); (2) operation of the probes to apply energy without creating a vapor layer, thereby achieving coagulation instead of

ablation (i.e., noninfringement of the '882 patent); and (3) operation of the probes as part of an "electrosurgical system" that does not have a fluid supply (i.e., noninfringement of the '536 patent).

The court is again unpersuaded by these arguments. The evidence of record for the '592 patent discussed above shows that the Saphyre, ElectroBlade, and Control RF probes were constructed to prevent the return electrode from contacting tissue. The court finds that similar evidence exists with respect to the '882 and '536 patents. In particular, Smith & Nephew refers to its Saphyre product line as "ablation" probes in its sales guides. (See PX 381 at 1, PX 390 at 10). Smith & Nephew also markets its Saphyre and Control RF probes for use in ablation, not coagulation, even though both may provide coagulation. (See PX 390 at 4, PX 593 at 11, 29, PX 205 at 1) Additionally, several witnesses at trial testified that the Saphyre, ElectroBlade, and Control RF probes must be used with electrically conducting fluid. (See D.I. 411 at 397-98, 405, 412; D.I. 414 at 848; D.I. 415 at 1013) More specifically, Mr. Sparks and Ms. Drucker testified that electrically conducting fluid must be delivered to the target site in arthroscopic surgery. (See D.I. at 814-16; D.I. 415 at 1013-14) A reasonable juror, taking all of this evidence into account, could have concluded that the accused probes were designed to infringe and that the occasional or

aberrant use of one of them in a non-infringing manner, as suggested by Smith & Nephew, does not constitute a substantial noninfringing use. Therefore, the court denies Smith & Nephew's motion for judgment as a matter of law that it is not liable for contributing to the infringement of the patents in suit.

As to a new trial, none of the reasons for granting a new trial exists in the instant case. That is, the jury's verdict is not against the weight of the evidence. Rather, both sides presented evidence to support their respective positions. Additionally, no miscarriage of justice will result by upholding the jury's verdict. For these reasons, the court denies Smith & Nephew's motion for a new trial on contributory infringement grounds.

5. Inducing Infringement

Smith & Nephew argues that it is not liable as an inducing infringer because Arthrocare failed to prove that Smith & Nephew intends to cause its customers to infringe the asserted claims of the patents in suit. The court finds that Smith & Nephew's arguments are not well founded and that sufficient evidence exists in the record to support the jury's verdict of inducing infringement. In particular, Ms. Knudsen and Mr. Heim testified that they read the patents in suit before the Saphyre probe design was complete and prior to design efforts commenced for the ElectroBlade and Control RF probes. (D.I. 415 at 991; D.I. 414 .

at 936-37, PX 735 at 23-25) They further stated that they evaluated Arthrocare's patented products prior to designing the accused products. (D.I. 414 at 951, D.I. 415 at 977-78) On this basis, a jury reasonably could have found that Smith & Nephew knew or should have known that its customers would directly infringe the patents in suit when using the Saphyre, ElectroBlade, and Control RF probes. Consequently, the court denies Smith & Nephew's motion for judgment as a matter of law that it is not liable for inducing infringement.

Regarding a new trial, the jury's verdict of inducing infringement is not against the clear weight of the evidence. Moreover, no miscarriage of justice will result if this verdict stands. Accordingly, the court concludes that a new trial is not warranted and denies Smith & Nephew's motion for a new trial on inducing infringement grounds.

D. Smith & Nephew's Renewed Motion for Judgment as a Matter of Law, or in the Alternative a New Trial, on Invalidity Grounds

Smith & Nephew renewed its motion for judgment as a matter of law that the patents in suit are invalid based on prior art grounds. Before reaching the substance of this motion, Arthrocare challenges Smith & Nephew's right to raise this motion claiming that Smith & Nephew failed to preserve the issue of invalidity before the case was submitted to the jury pursuant to Fed. R. Civ. P. 50(a). Rule 50(b) permits consideration of such renewed

motions for judgment as a matter of law only when a motion for a directed verdict has been made at the close of the evidence offered by an opponent. In pertinent part, Rule 50(b) states:

If, for any reason, the court does not grant a motion for judgment as a matter of law made at the close of all the evidence, the court is considered to have submitted the action to the jury subject to the court's later deciding the legal questions raised by the motion. The movant may renew its request for judgment as a matter of law by filing a motion no later than 10 days after entry of judgment.

Rule 50(a) requires that "[a] motion for a directed verdict shall state the specific grounds therefor." This requirement is in place to afford the non-moving party with the opportunity to reopen its case and present additional evidence. See Bonjorno v. Kaiser Aluminum & Chem. Corp., 752 F.2d 802, 814 (3d Cir. 1984) (citing Lowenstein v. Pepsi-Cola Bottling Co., 536 F.2d 9, 11 (3d Cir. 1976)).

In the case at bar, Smith & Nephew motioned for a directed verdict three times. It first made a Rule 50(a) motion at the close of Arthrocare's case. (See D.I. 415 at 1161) It made a second Rule 50(a) motion at the close of all the evidence. (See D.I. 417 at 1549) Smith & Nephew then renewed this motion prior to the jury charge. (See D.I. 418 at 1700) Since the issue of invalidity had not been presented when Smith & Nephew initially moved for a directed verdict, the court finds that Smith & Nephew's first motion was not directed to the invalidity of the patents in suit. The court notes, however, that the issue of

invalidity was in evidence at the time Smith & Nephew made its second and third motions. The court also notes that it indicated after these latter motions that Smith & Nephew's rights were reserved, despite the fact that Smith & Nephew did not specifically state the precise grounds for its motions. (See D.I. 417 at 1549; D.I. 418 at 1700). As well, the court did not require any argument concerning the motions when raised and precluded Smith & Nephew from discussing them. The court, therefore, concludes that it would be unjust to Smith & Nephew not to consider its renewed motion for judgment as a matter of law. Accordingly, the court will consider the instant motion.

1. The Legal Standard for Invalidity

A patent is presumed valid, and each claim whether in independent, dependent, or multiple dependent form is presumed to be valid independent of the validity of other claims. 35 U.S.C. § 282 (2003). The party asserting invalidity, consequently, has the burden of proof. Id. This burden is satisfied only by proving facts establishing invalidity by clear and convincing evidence. Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1377 (Fed. Cir. 2003) (citing Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc., 98 F.3d 1563, 1569 (Fed. Cir. 1996)). The patentee, therefore, need not submit any evidence to support the validity of a patent. Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1570 (Fed.

Cir. 1986). Moreover, the challenger's burden is especially difficult to meet when the art relied on at trial was considered by the PTO. BOC Healthcare, Inc. v. Nellcor, Inc., 892 F. Supp. 598, 602 (D. Del. 1995). Indeed, the Federal Circuit has stated:

When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents.

American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed. Cir. 1984).

a. Invalidity on Anticipation Grounds

A patent is invalid for anticipation under 35 U.S.C. § 102 if a single prior art reference explicitly discloses each and every limitation of the claimed invention. Lamar Marine, Inc. v. Baronet, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987). The Federal Circuit has stated that "[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention."

Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1576 (Fed. Cir. 1991). In determining whether a patented invention is explicitly anticipated, the claims are read in the context of the patent specification in which they arise and in which the invention is described. Glaverbel Societe Anonyme v.

Northlake Mktg. & Supply, Inc., 45 F.3d 1550, 1554 (Fed. Cir. 1995). The prosecution history and the prior art may be consulted if needed to impart clarity or to avoid ambiguity in ascertaining whether the invention is novel or was previously known in the art. Id.

A prior art reference also may anticipate without explicitly disclosing a feature of the claimed invention if that missing characteristic is inherently present in the single anticipating reference. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). The Federal Circuit has explained that an inherent limitation is one that is necessarily present and not one that may be established by probabilities or possibilities. Id. That is, "[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient." Id. The Federal Circuit also has observed that "[i]nherency operates to anticipate entire inventions as well as single limitations within an invention." Schering Corp. V. Geneva Pharms. Inc., 339 F.3d 1373, 1380 (Fed. Cir. 2003). Moreover, recognition of an inherent limitation by a person of ordinary skill in the art before the critical date is not required to establish inherent anticipation. Id. at 1377.

An anticipation inquiry involves two steps. First, the court must construe the claims of the patent in suit as a matter of law. See Key Pharms. v. Hercon Labs Corp., 161 F.3d 709, 714

(Fed. Cir. 1998). Second, the finder of fact must compare the construed claims against the prior art. Id. A finding of anticipation will invalidate the patent. Applied Med. Res. Corp. v. U.S. Surgical Corp., 147 F.3d 1374, 1378 (Fed. Cir. 1998)

i. The '536 Patent

Smith & Nephew charges that the '536 patent is anticipated by several prior art references. In particular, Smith & Nephew contends that the '499 patent, the '007 patent, the '198 patent, and the Elsasser/Roos article each disclose all of the limitations of the invention claimed in the '536 patent. As support for its anticipation argument, Smith & Nephew asserts that its expert Dr. Taylor testified that the '198, '499, and '007 patents and the Elsasser/Roos article individually disclose every limitation recited in claims 45, 46, and 56 of the '596 patent. (See D.I. 416 at 1294-1313) Smith & Nephew also contends that Arthocare did not offer any evidence to contradict or rebut this testimony, but instead cross-examined Dr. Taylor about select claim limitations to confuse and mislead the jury.

Viewing the record in a light most favorable to Arthocare as the verdict winner, the court is unpersuaded by Smith & Nephew's argument. The evidence presented at trial reasonably supports the jury's verdict of infringement. The PTO specifically considered the prior art effect of the '499 and '007 patents during the prosecution of the '536 patent and allowed the

asserted claims. The PTO also considered the '198 patent and the Elsassser/Roos article during the reexamination of the '536 patent and issued a notice of intent to issue reexamination certificate. (See D.I. 417 at 1537-1540) The court concludes that this evidence was sufficient to convince a jury of the validity of the '536 patent.

Additionally, Arthocare solicited testimony from Dr. Taylor establishing that each of the asserted references fails to disclose at least one limitation of the asserted claims. Dr. Taylor admitted on cross-examination that the '499 patent does not disclose a current flow path through electrically conducting fluid as required by the asserted '536 claims. Dr. Taylor testified that it instead discloses inserting the electrodes directly into the target tissue, thereby facilitating electrical current flow between the axial and outer electrodes through the tissue. (See D.I. 416 at 1409-12) Dr. Taylor also stated in his deposition that both electrodes disclosed in the '007 patent have substantially the same current density (i.e., meaning that the '007 patent did not disclose a return electrode), though asserted at trial that his deposition testimony was in error. (See id. at 1383-85) Dr. Taylor likewise testified that the '007 patent and the '198 patent do not disclose the location of a connector with respect to the proximal end of the shaft as required by the asserted claims. (See id. at 1400; 1371) Additionally, Dr.

Taylor testified that the Elsasser/Roos article fails to explicitly describe the function for the structure located at the proximal end of the disclosed probe. (See id. at 1298) Dr. Taylor further testified on cross-examination that neither the '198 patent nor the Elsasser/Roos article disclose the use of either saline or Ringer's lactate, both of which are electrically conducting fluids. (See id. at 1340-43) Dr. Taylor, in fact, stated that the references do not distinguish between the electrically non-conducting liquid used with monopolar devices and the liquid used in bipolar devices. (Id.) Moreover, Dr. Taylor stated that there would be no need for the steel band described in Figure 5 of the '198 patent if the liquid shown in Figure 5 was electrically conducting. (See id. at 1345) Given the totality of this evidence, a jury may have properly found that the prior art references do not anticipate the '536 invention. Therefore, the court denies Smith & Nephew's motion for judgment as a matter of law that the asserted claims of the '536 patent are invalid on anticipation grounds.

With respect to a new trial, no miscarriage of justice will result if the jury's verdict of validity as to the '592 patent stands. Mindful not to substitute its own judgment of the facts and the credibility of the witnesses for those of the jury, the verdict is neither against the weight of the evidence nor facially inconsistent. Furthermore, since the conclusion of

trial, no new evidence has surfaced to alter the outcome of the trial. The court, consequently, denies Smith & Nephew's motion for a new trial on anticipation grounds for the '592 patent.

ii. The '882 Patent

Smith & Nephew contends that the '138 patent and the Slager article individually disclose each and every limitation recited in the asserted claims of the '882 patent. Smith & Nephew specifically argues that the '138 patent anticipates claims 1, 13, and 54 and that the Slager article anticipates claims 1, 13, 17, and 54. Smith & Nephew relies on the expert testimony of Dr. Taylor and Dr. Kim Manwaring for support. (See id. at 1313-1320; D.I. 414 at 886-96) As with the '536 patent discussed above, Smith & Nephew maintains that Arthocare failed to present rebuttal evidence to contradict the experts, but instead misleadingly cross-examined these experts regarding particular claim limitations to confuse the jury.

The court, nonetheless, finds that a reasonable jury could have concluded on the record before it that several differences exist between the '882 invention and the '138 patent and the Slager article such that Smith & Nephew failed to prove anticipation by clear and convincing evidence. Focusing first on the '138 patent, Dr. Manwaring admitted that this reference discloses a spark discharge followed by vaporization of the fluid. (See id. at 907-908) In contrast, claims 1, 13, 17, and

54 of the '882 patent disclose vaporization of the electrically conducting fluid followed by electrical discharge. Claim 13 also requires generation of photons having a wavelength in the ultraviolet spectrum. Dr. Manwaring stated at trial that the '138 patent does not explicitly mention ultraviolet photons and that he was unaware of any testing that established that the '138 device emits ultraviolet photons. (See id. at 897-98) Similarly, Dr. Taylor confirmed that he performed no testing to establish that a device built according to the '138 patent generates ultraviolet light. (See D.I. 416 at 1420-21) Finally, claim 54 of the '882 patent discloses evacuating the fluid beyond the vicinity of the target tissue. Both Dr. Manwaring and Dr. Taylor admitted that the '138 patent, in contrast, discloses drawing the fluid into the catheter tip where it remains in the vicinity of the target tissue. (See D.I. 414 at 904-05; D.I. 416 at 1432-33)

Turning to consider the Slager article, Dr. Taylor agreed that it does not disclose the application of energy to a "target site on a patient body structure" as required by the preamble of claims 1 and 28. Dr. Taylor instead testified that the Slager article discussed the application of energy to a tissue in a lab dish. (See id. at 1426-27) Since sufficient evidence exists for the jury to have concluded that the '138 patent and the Slager article do not disclose each and every limitation found in the

claims of the '882 patent, Smith & Nephew is not entitled to prevail on its motion for judgment as a matter of law. The court, consequently, denies Smith & Nephew's motion for judgment as a matter of law that the '882 patent is invalid on anticipation grounds.

Addressing Smith & Nephew's motion for a new trial on anticipation grounds, Smith & Nephew has failed to demonstrate that the verdict is against the weight of the evidence or that a new trial is necessary to remedy a miscarriage of justice. For these reasons, the court denies Smith & Nephew's motion for a new trial on anticipation grounds as to the '882 patent.

iii. The '592 Patent

Smith & Nephew asserts that the '007 patent and the Slager article each recite all the limitations of the asserted claims of the '592 patent. Smith & Nephew relies on Dr. Taylor's testimony to support this anticipation argument and, as with the '536 and '882 patents, again claims that Arthocare failed to elicit any rebuttal testimony. Rather, Smith & Nephew charges that Arthocare misleadingly cross-examined Dr. Taylor regarding certain claim limitations to cause confusion among the jurors.

Substantial evidence exists in the record to distinguish the '592 invention from the cited prior art references in support of the jury's verdict of validity. The '592 patent contains the same "return electrode" limitation as the '536 patent. As

discussed above in relation to the '536 patent, the '007 patent does not disclose a return electrode limitation. Additionally, the '007 patent fails to disclose the waveform necessary to determine whether it anticipates the 500 to 1,400 volts peak to peak recited in claim 21.¹⁰ Dr. Taylor admitted that when he opined that the '007 patent discloses a voltage in the range of 500 to 1,400 volts peak-to-peak, he presumed that the wave form was a sine wave since this is the most common form used. (See id. at 1401-1404) In light of this presumption, a jury reasonably may have dismissed Dr. Taylor's testimony concerning the anticipatory effect of the '007 patent on the '592 patent. As to the Slager article, claims 1 and 28 of '592 patent contain the same "on or within a patient's body" preamble language as claims 1 and 26 of '882 patent. The Slager article, on the other hand, only discloses the application of energy to tissue in a lab dish as noted above. Furthermore, claims 1 and 23 of the '592 patent specify that the return does not touch the body structure. Dr. Taylor testified that he was unable to determine the location

¹⁰The '007 patent discloses a 20 to 200 root-mean-square voltage. Presume that the wave form produced by the generator is a sine wave, the court acknowledges that this root-mean-square voltage range may be converted to a peak-to-peak voltage using a 2.83 conversion factor. Applying this factor to the voltage range disclosed in the '007 patent, the resulting peak-to-peak voltage for the 200 volts root mean square is 583 volts peak-to-peak. However, using the conversion factor of 2 for a square wave, the 200 volts root-mean-square converts to 400 volts peak-to-peak.

of the return electrode in the Slager article. (See id. at 1414-18) Given this evidence of the differences between these prior art references and the claimed invention, the jury verdict was not erroneous. Accordingly, the court denies Smith & Nephew's motion for judgment as a matter of law that the '592 patent is invalid on anticipation grounds.

The court also denies Smith & Nephew's motion for a new trial as to the '592 patent. None of the common reasons for granting a new trial exist under the facts at bar. That is, the jury's verdict is not against the weight of the evidence or facially inconsistent. Likewise, no miscarriage of justice will result if the verdict stands.

b. Invalidity on Enablement Grounds

The statutory basis for the enablement requirement is found in 35 U.S.C. § 112, paragraph 1, which provides in relevant part:

The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In order to be enabling, a specification must teach those skilled in the art how to make and to use the full scope of the claimed invention without undue experimentation. Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1365 (Fed. Cir. 1997). The Federal Circuit has explained that "patent protection is granted in

return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable ... Tossing out the mere germ of an idea does not constitute enabling disclosure." Id. at 1366.

In determining whether undue experimentation is required to practice a claimed invention, a court may consider several factors, including: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance disclosed in the patent; (3) the presence or absence of working examples in the patent; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (6) the predictability of the art; and (7) the breadth of the claims. In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). Consideration of each of these factors, however, is not a mandatory part of a court's analysis. Rather, a court is only required to consider those factors which are relevant to the facts of each case. See Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1213 (Fed. Cir. 1991). Thus, the enablement requirement is a question of law based on underlying factual inquiries. In re Wands, 858 F.2d at 737.

Smith & Nephew argues that the asserted claims in the '882 patent are not properly enabled because the "cold ablation"

process is not adequately described in the specification.¹¹ The '882 specification states that the cold ablation process is dependent upon a variety of factors including "the number of electrode terminals, electrode size and spacing, electrode surface area, asperities and sharp edges on the electrode surfaces, electrode materials, applied voltage and power, current limiting means, such as inductors, electrical conductivity of the fluid in contact with the electrodes, density of the fluid, and other factors." ('882 patent, col. 11 at ll. 8-13) Smith & Nephew contends that while the requisite variables are enumerated in the specification, it fails, nevertheless, to specify what particular combination should be used to achieve optimal cold ablation. Smith & Nephew supports this argument with Dr. Taylor's testimony regarding preferred voltage ranges, materials, frequencies, fields, power levels, contract surface area values and distances for the active electrode. (See D.I. 416 at 1436-38)

The jury, however, reasonably may have disregarded Dr. Taylor's testimony, finding it to be both conclusory and entirely solicited by counsel's line of direct questioning. Dr. Taylor testified that he "blanked" on invalidity grounds other than

¹¹The cold ablation process involves "applying a high frequency voltage between the active electrode and the return electrode to develop high electric field intensities in the vicinity of the target tissue site." ('882 patent, col. 10 at ll. 41-44) The high electric field causes the tissue to completely disintegrate. (Id. at ll. 44-54)

anticipation; consequently, he was led into a discussion of enablement by trial counsel. In relevant part, Dr. Taylor testified as follows:

Q: Do you have any other basis for believing that the claims of the '882 patent are invalid?

A: I am sorry, I am blanking on this.

* * *

Q: Does the '882 patent teach anything about how to achieve a new phenomenon that is different than the principle of operation of conventional electrosurgical devices?

A: No, it doesn't. I was perplexed and, frankly, am still perplexed about the overall phenomenon of [c]oblation.

Q: And is that defense also sometimes called nonenablement?

A: Yes, it is.

Q: Do you have an opinion as to whether the claims of the '882 patent are enabled to the extent it claims a new phenomenon?

A: Yes, I have an opinion.

Q: What is that opinion?

A: That it is not.

Q: Thank you.

(Id. at 1323-1325) (emphasis added) Based on the above record, the jury had sufficient grounds to conclude that Smith & Nephew had failed to prove by clear and convincing evidence that the '882 patent was not enabled and invalid. In turn, the court denies Smith & Nephew's motion for judgment as a matter of law that the '882 patent is invalid on enablement grounds.

Regarding a new trial, the verdict was not against the clear weight of evidence. Likewise, the jury's verdict will not lead to a miscarriage of justice. Thus, the court denies Smith &

Nephew's motion for a new trial on enablement grounds as to the '882 patent.

E. Smith & Nephew's Motion for A New Trial on the Basis of Improperly Admitted/Excluded Evidence

Smith & Nephew contends that the court erred in admitting and excluding select evidence such that a new trial is warranted. Specifically, Smith & Nephew argues that the following evidence was improperly excluded: (1) Arthrocare's sworn 510(k) submissions to the Food and Drug Administration ("FDA"); (2) testimony regarding those submissions from Dr. Hira A. Thapliyal, a co-inventor named on the patents in suit; (3) testimony regarding the certificate of correction from Mr. Warren Heim, a consultant to Smith & Nephew from Team Medical; (4) Judge Orrick's opinion that the '198 patent anticipated one of the patents in suit; and (5) testimony from Dr. Manwaring regarding ultraviolet photon emission test results. Smith & Nephew also contends that evidence of copying and Smith & Nephew marketing documents were improperly admitted. Federal Rule of Civil Procedure 61 requires a court to disregard harmless evidentiary errors. In pertinent part, Rule 61 states:

No error in either the admission or the exclusion of evidence . . . is ground for granting a new trial . . . unless refusal to take such action appears to the court inconsistent with substantial justice. The court at every stage of the proceeding must disregard any error or defect in the proceeding which does not affect the substantial rights of the parties.

A court's inquiry in evaluating a motion for a new trial on the basis of trial error is, therefore, twofold: "(1) whether an error was in fact committed, and (2) whether that error was so prejudicial that denial of a new trial would be 'inconsistent with substantial justice.'" Finch v. Hercules Inc., 941 F. Supp. 1395, 1414 (D. Del. 1996) (internal citation omitted). With respect to the second prong of this two-part test, a new trial must be granted unless "it is highly probable that [the erroneous ruling] did not affect the [objecting party's] substantial rights." Bhaya v. Westinghouse Electric Corp., 709 F. Supp. 600, 601 (E.D. Pa. 1989) (quoting McQueeney v. Wilmington Trust Co., 779 F.2d 916, 928 (3d Cir. 1985)).

The court has reviewed its rulings concerning the evidence in issue consistent with the first prong and finds no error was in fact committed. As such, the court need not consider whether denial of a new trial would be inconsistent with substantial justice as set forth in the second prong. The court considers each item of evidence in dispute in further detail below.

1. Exclusion of Arthrocare's FDA 510(k) Submissions and Dr. Thapliyal's Testimony

Smith & Nephew argues that Arthrocare's 510(k) submissions to the FDA and Dr. Thapliyal's testimony regarding those submissions qualify as admissions against interest by a party opponent and should have been admitted into evidence as relevant

to the issues of anticipation and enablement.¹² In particular, Smith & Nephew charges that the submissions demonstrate that the commercial embodiments of the patents in suit have the same principles of operation as prior art devices. The court rejects Smith & Nephew's argument and maintains that these submissions are irrelevant to invalidity, just as the court originally concluded when it ruled on Smith & Nephew's motion in limine. (See D.I. 367 at ¶15; D.I. 410 at 193) Anticipation is determined by comparing the limitations of the asserted claims, not of commercial embodiments as described in 510(k) submissions, to the disclosure found in a single piece of prior art. Enablement is evaluated based on the teachings found in the specification, not on those present in 510(k) submissions. Therefore, since the 510(k) submissions are not relevant to the substantive issues at bar, the exclusion of these documents and corresponding testimony was not in error. Accordingly, the court denies Smith & Nephew's motion for a new trial on the basis of the exclusion of Arthrocare's 510(k) submissions and Dr. Thapliyal's testimony about these submissions.

¹²A 510(k) submission to the FDA is a "submittal[] of engineering and clinical information which [is] provided to the FDA to permit that agency to assess the safety and effectiveness of a new product with regard to a predicate product which is already on the market." Sunrise Med. HHG, Inc. v. AirStep Corp., 95 F. Supp. 2d 348, 405 (W.D. Pa. 2000).

2. Exclusion of Mr. Heim's Testimony

Smith & Nephew argues that it sought to introduce testimony at trial from Mr. Heim to support its argument that the certificate of correction was invalid. Specifically, Smith & Nephew contends that Mr. Heim was prepared to testify that he did not recognize the possibility of an error in the "active electrode" claim language found in the '882 patent as originally issued prior to the certificate of correction. On review, the court finds that its decision to limit Mr. Heim's testimony to the subject matter of his deposition was correct.

Federal Rule of Civil Procedure 37(c)(1) provides in pertinent part:

A party that without substantial justification fails to disclose information required by Rule 26(a) or 26(e)(1), or to amend a prior response to discovery as required by Rule 26(e)(2), is not, unless such failure is harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed.

The court excluded this testimony because Mr. Heim did not discuss the substance of his trial testimony in his deposition. That is, approximately one week prior to the start of trial, Arthocare deposed Mr. Heim and asked him what he expected to testify about at trial. Smith & Nephew counsel instructed Mr. Heim not to respond to the question citing attorney-client privilege and the work product doctrine. Finding such instruction to be improper gamesmanship under Rule 37(c), the

court limited Mr. Heim's testimony to the substance of his deposition testimony. (See D.I. 413 at 944) Additionally, the court is troubled by Smith & Nephew's use of Mr. Heim's testimony. Despite identifying him as a fact witness, Smith & Nephew appears to employ him as an expert concerning the validity of the certificate of correction. (See id. at 939) In light of both these concerns, the court denies Smith & Nephew's motion for a new trial on grounds that Mr. Heim's testimony was improperly limited.

3. Exclusion of Judge Orrick's Opinion

Smith & Nephew argues that the findings of fact relating to the '536 and '882 patents made by Judge Orrick following a preliminary injunction hearing during the course of the Arthocare v. Ethicon, Inc. litigation are relevant to both the presumption of validity and the validity of the '536 and '882 patents. In particular, Smith & Nephew charges that Judge Orrick's determination that the '198 patent describes "a bipolar electrosurgery device intended to be used in electrically conductive fluid, with electrical current flowing between the active and return electrodes through the fluid" should have been admitted since the parties at bar dispute whether the '198 patent discloses electrically conducting fluid. (D.I. 321, ex. A at 17) The court disagrees. Judge Orrick rendered his findings of fact in the context of a preliminary injunction motion and concluded

that there were substantial questions about the validity of claim 45 of the '536 patent, claims 1, 26, 28, and 32 of the '882 patent, claims 40 and 44 of the '909, and claim 101 of the '281 patent. His interlocutory decision does not alter the presumption of validity; a patent is presumed valid and remains so unless and until final judgment is entered otherwise. See 35 U.S.C. §282 (2003). Additionally, findings of fact made in litigation unrelated to the present suit do not have a presumptive effect. In the instant litigation, the jury was charged with determining the validity of the asserted patents after considering the evidence presented at trial in accordance the court's instructions. Any reference to Judge Orrick's opinion potentially would have confused the jury regarding their role in deciding such validity. Moreover, the burdens of proof associated with a preliminary injunction hearing differ from those employed at trial. In this regard, the Federal Circuit has observed that "[v]alidity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial." Amazon.com v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1358 (Fed. Cir. 2001). Consequently, the court denies Smith & Nephew's motion for a new trial on the basis the exclusion of Judge Orrick's opinion.

4. Limitation of Dr. Manwaring's Testimony To His Expert Report

Smith & Nephew contends that Dr. Manwaring should have been permitted to testify at the trial about whether the Codman ME2¹³ emits ultraviolet photons and about testing conducted by Dr. Skromme to prove such emission. Smith & Nephew argues that this testimony was relevant to enable the jury to assess whether the Codman ME2 anticipates the asserted claims that have ultraviolet photon emissions as a limitation. However, Smith & Nephew did not produce Dr. Skromme's report until two days before Dr. Manwaring was scheduled to testify after the start of trial. Because Arthrocare was not afforded the opportunity to take discovery on the test results or to depose Dr. Skromme, the court excluded such evidence at trial, consistent with Rule 37(c)(1). The court, therefore, denies Smith & Nephew's motion for a new trial on the basis of the exclusion of Dr. Manwaring's testimony about ultraviolet photon emission testing.

5. Admission of Evidence of "Copying"

Smith & Nephew argues that admission of evidence of "copying" infected the entire trial and improperly inflamed the jury. In this regard, Smith & Nephew employees read the patents in suit and evaluated Arthrocare's patented products prior to

¹³The Codman ME2 is a commercial product embodied by the '158 or '138 prior art patent.

designing the accused products. (See D.I. 412 at 626-633; D.I. 415 at 1160-61; D.I. 417 at 1507-1508)

Prior to trial, in order to avoid any inferences of copying, Smith & Nephew made the strategic decision to withdraw its defense of obviousness and to stipulate to its knowledge of the patents in suit. Nevertheless, after a vigorous motion practice and lengthy discussions, the court concluded that the evidence was still relevant to the issue of inducing infringement. More specifically, in order to prove that Smith & Nephew induced infringement, it was Arthrocare's burden to prove that Smith & Nephew intended to encourage or to instruct its customers to directly infringe. Evidence of copying was appropriate circumstantial evidence going to intent; that is, if Smith & Nephew used Arthrocare's patented products as a template for its own, that would be circumstantial evidence that Smith & Nephew knew or should have known that its customers would directly infringe the patents in suit by using the Saphyre, ElectroBlade, and Control RF probes.¹⁴

At trial, Smith & Nephew presented evidence that it is customary and not inappropriate to evaluate competitors'

¹⁴It is ironic that Smith & Nephew, post-trial, argues that Arthrocare has not satisfied its burden of proving intent, based on the very evidence described above. See *supra*, Section IV, C, 5. Clearly, then, the fact of knowledge is not a sufficient basis for proving inducement and the evidence of intent is relevant.

products, and that it designed its own products without copying Arthrocare's patented products. (See D.I. 412 at 651-54; D.I. 414 at 951-53; D.I. 417 at 1507-08) Smith & Nephew was not prejudiced with respect to its ability to present the technical merits of its noninfringement and invalidity defenses to the jury. (See, e.g., D.I. 412 at 715-32; D.I. 414 at 805-822, 883-896, 962-970; D.I. 415 at 976-983; 999-1039; 1198-1227; D.I. 416 at 1288-1334; D.I. 417 at 883-896) Arthrocare, in turn, presented evidence to the contrary. (See, e.g., D.I. 411 at 376-500) Given the time spent on this noninfringement and invalidity evidence during the course of a nine-day jury trial, it cannot be said that disputed evidence relating to "copying" was disproportionately emphasized or time-consuming.

For all of these reasons, the court concludes that it was not error to admit evidence of "copying" and that such admission does not present grounds for a new trial.

6. Admission of Smith & Nephew Marketing Documents¹⁵

¹⁵Smith & Nephew failed to identify precisely which marketing documents that it believes were erroneously admitted. The court, consequently, is left to presume that Smith & Nephew is uniformly referring to any marketing type of document entered into evidence including the "Dyonics Control RF System" Sales Guide, "Saphyre Bipolar Ablation Probes" Sales Guide, "Instructions for Use Dyonics Series 7000 RF Arthroscopic Probe," "Competitive Selling Arthrocare," and the "Dyonics Series 9000 Electrode Blade Resector." (See, e.g., PX 593, PX 390, PX 205, PX 324, PX 335)

Smith & Nephew claims that admission of its marketing documents, which appear to characterize Arthrocare's patent position as "strong," were irrelevant and inflammatory. Smith & Nephew contends that these documents could only be relevant to the issues of obviousness and its knowledge of the patents, but that neither were in dispute at trial.¹⁶ Moreover, Smith & Nephew argues that the opinions of its marketing and sales personnel regarding the strength of Arthrocare's patents are irrelevant.

The court finds that Smith & Nephew's marketing documents are relevant to the inducing infringement cause of action and, as such, that it did not err in admitting this evidence at trial. As the court discussed above in relation to evidence of "copying," Smith & Nephew's marketing documents are circumstantial evidence of Smith & Nephew's intent to induce infringement. These documents show how the alleged infringing products function and give instruction how to operate them. The court concludes that such information bears upon the manner in which Smith & Nephew encouraged its users to infringe Arthrocare's patents. Accordingly, the court denies Smith & Nephew's motion for a new trial on the basis the court's admission of Smith & Nephew's marketing documents.

¹⁶As mentioned above, Smith & Nephew withdrew its obviousness defense prior to trial and stipulated to its knowledge of the patents in suit during trial.

**F. Smith & Nephew's Motion for A New Trial on the Basis of
The Court's Jury Instructions**

Smith & Nephew asserts that the court's instruction on infringement was "hopelessly confusing" for the jury when read in light of the court's claim construction for the "contact" limitation recited in claim 47 of the '536 patent and all of the asserted claims of the '592 patent.¹⁷ The court instructed the jury as follows concerning infringement:

In this case, Arthocare contends that Smith & Nephew's accused products and methods literally infringe the asserted claims. In order to prove that any one of the asserted claims is literally infringed, Arthocare must prove by a preponderance of the evidence that Smith & Nephew's accused products or methods include each and every limitation of that particular claim. In other words, you must compare the features of the accused products or methods with the limitations of each asserted claim in order to determine whether the accused products or methods include each and every limitation of an asserted claim.

With respect to the asserted claims of the '592 and '882 patents, the accused methods need not always practice the invention of any asserted method claim, so long as Arthocare has proven by a preponderance of the evidence that the accused methods operate in a way that meet each and every step of the method described in the claim some of the time.

(D.I. 418 at 1716) The court further instructed the jury as follows concerning the "contact" limitation:

The claim limitation the return electrode is not in contact with the body structure is clear -- the return electrode is not to contact the body at all during the performance of the claimed method. The claimed method

¹⁷Smith & Nephew objected to the these instruction at the charge conference. (See D.I. 416 at 1239-1241; D.I. 417 at 1469-1473)

does not contain any time limitations. Thus, the claimed method is performed when each of the three steps of the claim has been completed.

(Id. at 1718) Specifically, Smith & Nephew appears to argue that the source of the confusion lies in the juxtaposition of the language "at all" in the infringement instruction with the language "some of the time" in the claim construction instruction. Smith & Nephew argues that the jury may have read these instructions and thought that infringement occurred if the return electrode was not always in contact with the tissue.

Where the basis for seeking a new trial is an alleged error in the jury instructions, the error must be "so substantial that, viewed in light of the evidence in the case and the charge as a whole, the instruction was capable of confusing and thereby misleading the jury." Link v. Mercedes-Benz of North America, Inc., 788 F.2d 918, 922 (3d Cir. 1986). After reviewing the jury charge as a whole in light of the evidence presented in this case, the court cannot conclude that the jury instructions confused or misled the jury into believing that the accused products infringe the asserted claims if they are not in continual contact with tissue to warrant a new trial. The court instructed the jury separately regarding infringement and its claim construction, and both instructions properly stated the law. As well, the jury was asked to complete a special verdict form that explicitly separated the types of infringement, the

patents in suit, the asserted claims of each patent, and the accused infringing products. As a result of this separation, the jury was required to make finite determinations concerning whether a particular claim in a particular patent was infringed in a particular way by a particular product. Furthermore, the court finds no evidence to suggest that the jury was "hopelessly confused." The jury did not ask the court to clarify any of its instructions or pose any questions to the court during deliberations. The jury also did not incur any difficulty in completing the special verdict form as they entered responses in all required fields. (See D.I. 405) Therefore, the court denies Smith & Nephew's motion for a new trial on the basis of the court's jury instructions.

G. Smith & Nephew's Motion for A New Trial On the Grounds That the Validity of the Certificate of Correction Was Decided by the Jury

Smith & Nephew avers that the district court is better suited to decide the validity of the certificate of correction than a jury because such determination involves both a review of the factual determinations of a government agency and the legal decisions about the nature of the underlying mistake. The court disagrees. Smith & Nephew did not object to submitting this issue to the jury at any time during the trial or prior to the jury charge. Smith & Nephew appears now to raise this objection in the face of an unfavorable jury verdict. Even assuming,

arguendo, that the court did err in submitting this issue to the jury, the court, nevertheless, agrees with the jury's verdict that the certificate of correction is valid. The court, consequently, denies Smith & Nephew's motion for a new trial on the grounds that the validity of the certificate of correction was decided by the jury.

H. Smith & Nephew's Motion for A New Trial on the Basis of Arthrocare's Refusal to Limit the Issues at Bar

Smith & Nephew complains that it was allocated insufficient time to adequately try the number of issues presented by Arthrocare. As described by Smith & Nephew, Arthrocare asserted sixteen claims from three patents against three Smith & Nephew products.¹⁸ As a result, according to Smith & Nephew, the verdict form required the jury to make 107 separate factual findings, which it did in only 4.5 hours, thereby spending just over two minutes per finding.¹⁹

¹⁸In reality, Arthrocare asserted only six independent claims from three patents. All three patents involved the same technology and contained many identical claim limitations. Indeed, two of the patents share the same specification.

¹⁹Making such arguments is a dangerous business in Delaware, where so many patent cases are tried. The court could, for instance, cite to the case of KLA-Tencor Corporation v. ADE Corporation, Civ. No. 00-892-KAJ, where the jury returned a verdict in February 2004 on 17 issues in approximately 37 minutes, likewise spending just over two minutes per finding. The court suspects, however, that counsel for Smith & Nephew will not be complaining about that result, since it was favorable to its client in that case.

The court starts with the proposition, not really in issue here, that a district court has the inherent power to manage its docket. See, e.g., Duquesne Light Co. v. Westinghouse Elec. Corp., 66 F.3d 604, 609 (3d Cir. 1995). There are a finite number of trial hours in a calendar year. If the court failed to manage its caseload, parties would get to trial in four or five years, rather than 18 to 24 months. Therefore, in every civil case, the court determines the number of hours in which each party will be required to present its evidence and arguments to the jury. This decision is based on the court's calendar, its experience, and its review of the pretrial order submitted by the parties at bar. The number of hours allocated to the instant case was fair, based upon that review.²⁰ The record demonstrates that it was not lack of time that dictated the results in this case,²¹ but the evidence presented by Arthrocare. Accordingly, the court denies Smith & Nephew's motion for a new trial on the basis of Arthrocare's refusal to limit the issues at bar.

²⁰The court had assigned several more hours to this case, but postponed trial for a day (and, thus, reduced the total number of hours available for trial) at Smith & Nephew's request. In connection with this latter request, made the day before trial commenced, the court tried to, but could not, accommodate a further postponement of trial, based on a multitude of considerations, as discussed with counsel. (See D.I. 382, 390, 409)

²¹The court notes in this regard that Smith & Nephew's decision to dismiss its obviousness defense was as much related to evidentiary concerns as it was to trial management concerns. (See D.I. 409 at 16-17; see also supra, Section IV, E, 5)

I. Arthrocare's Motion for Entry of Judgment of No Inequitable Conduct and Smith & Nephew's Cross Motion to Strike Arthrocare's Motion for Entry of Judgment of No Inequitable Conduct²²

Smith & Nephew alleges that Arthrocare committed inequitable conduct for each of the patents in suit: (1) during the prosecution of the '592 patent by informing the examiner that the '198 patent did not disclose the use of electrically conductive fluid and by not disclosing Judge Orrick's opinion; (2) during the reexamination of the '536 patent by failing to disclose Smith & Nephew's summary judgment briefs, Dr. Taylor's expert report, and the Roos declaration directed toward the issue of invalidity, and by engaging in improper "off-the-record" telephone conversations with the examiner regarding the merits of the '536 reexamination prior to the first substantive exam; and (3) during the process of obtaining the certificate of correction for the '882 patent by making two affirmative misrepresentations and by failing to explain how the so-called "correction" would broaden the scope of the claims.²³ Smith & Nephew charges that Mr. John Raffle,

²²Since the parties' cross motions are interrelated and focus of the issue of inequitable conduct, the court will consider their respective arguments together.

²³In granting the parties' request to file motions regarding inequitable conduct, the court indicated that such briefing was to be based upon the record established at trial. Therefore, to the extent that either party raised evidence not of record in their respective motions at bar, the court will ignore such evidence in deciding the instant motions. The court notes that Smith & Nephew seeks leave to depose the examiner responsible for

Arthrocare's in-house counsel responsible for prosecution of the '592 patent, misled the examiner concerning the use of electrically conductive fluid. Smith & Nephew claims that Mr. Raffle knew that claim 1 of the '198 patent recited "liquid to provide electrical conductance," but failed to call the examiner's attention to this limitation. In response to a February 29, 2000 office action issued by the examiner,²⁴ Mr. Raffle instead responded that "[t]he '198 patent never describes the use of 'electrically conductive fluid' during electrosurgery. The Roos '198 [p]atent only discloses the use of an unspecified 'washing liquid' that flows through the endoscope that houses the treatment and neutral electrodes. . . . The Roos '198 [p]atent does not state that the 'washing liquid' that is supplied to the region of the surgical site is electrically conductive fluid." (D.I. 428, ex. B at B23) Mr. Raffle also directed the examiner's attention to the '667 patent to substantiate his argument since this reference explains that "the device described in the

the reexamination of the '536 patent to determine the contents of his "off-the-record" conversation with Arthrocare's in-house counsel. The court denies this request.

²⁴The examiner stated:
Claims 80, 81, 83-85 . . . are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Roos The device includes a spaced return electrode as shown by Figure 1. A washing fluid passes through the axial lumen of the device. Since the return electrode is removed from the body structure, a conductive fluid must complete the current flow path.
(D.I. 428, ex. B at B17)

. . . '198 [p]atent[] did not work to cut tissue because the medium in contact with the electrodes was not electrically conductive." (*Id.* at B24) Smith & Nephew further argues that Arthrocare's inequitable conduct in connection with any one of the '592, '536, or '882 patents taints the enforceability of the remaining patents in suit. Arthrocare rebuts these assertions in their entirety and moves the court to enter a judgment of no inequitable conduct.

Applicants for patents and their legal representatives have a duty of candor, good faith, and honesty in their dealings with the PTO. Mollins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995); 37 C.F.R. § 1.56(a) (2003). This duty is predicated on the fact that "a patent is an exception to the general rule against monopolies and to the right of access to a free and open market." Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945). The duty of candor, good faith, and honesty includes the duty to submit truthful information and the duty to disclose to the PTO information known to the patent applicants or their attorneys which is material to the examination of the patent application. Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F.3d 28, 30 (Fed. Cir. 1999). A breach of this duty constitutes inequitable conduct. Mollins, 48 F.3d at 1178. If it is established that a patent applicant engaged in inequitable conduct with respect to one claim, then

the entire patent application is rendered unenforceable.

Kingsdown Med. Consultants v. Hollister Inc., 863 F.2d 867, 877 (Fed. Cir. 1988). A trial court may look beyond the final claims to their antecedents in determining inequitable conduct. Fox Indus., Inc. v. Structural Pres. Sys., Inc., 922 F.2d 801, 803 (Fed. Cir. 1990). "Claims are not born, and do not live, in isolation. Each is related to other claims, to the specification and drawings . . . [and] to earlier or later versions of itself in light of amendments made to it." Kingsdown, 863 F.2d at 874 (footnote omitted).

In order to establish unenforceability based on inequitable conduct, a defendant must establish by clear and convincing evidence that: (1) the omitted or false information was material to patentability of the invention; or (2) the applicant had knowledge of the existence and materiality of the information; and (3) the applicant intended to deceive the PTO. Mollins, 48 F.3d at 1178. A determination of inequitable conduct, therefore, entails a two step analysis. First, the court must determine whether the withheld information meets a threshold level of materiality. A reference is considered material if there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. Allied Colloids, Inc. V. American Cyanamid Co., 64 F.3d 1570, 1578 (Fed. Cir. 1995) (citations omitted). . A

reference, however, does not have to render the claimed invention unpatentable or invalid to be material. See Merck v. Danbury Pharmacal, 873 F.2d 1418 (Fed. Cir. 1989).

After determining that the applicant withheld material information, the court must then decide whether the applicant acted with requisite level of intent to mislead the PTO. See Baxter Int'l, Inc. V. McGaw Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998). "Intent to deceive cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for finding a deceptive intent." Herbert v. Lisle Corp., 99 F.3d 1109, 1116 (Fed. Cir. 1996). That is, "the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." Kingsdown, 863 F.2d at 876. A "smoking gun" is not required in order to establish an intent to deceive. See Merck, 873 F.2d at 1422. An inference of intent is warranted where a patent applicant knew or should have known that the withheld information would be material to the PTO's consideration of the patent application. Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997).

Once materiality and intent to deceive have been established, the trial court must weigh them to determine whether the balance tips in favor of a conclusion of inequitable conduct.

N.V. Akzo v. E.I. DuPont de Nemours, 810 F.2d 1148, 1153 (Fed. Cir. 1988). The showing of intent can be proportionally less when balanced against high materiality. Id. In contrast, the showing of intent must be proportionally greater when balanced against low materiality. Id.

If an original patent is found unenforceable for inequitable conduct, descendent patents which are genealogically related to the original patent, such as continuations, continuations-in-part, or divisionals, may also be rendered unenforceable. See East Chicago Mach. Tool Corp. v. Stone Container Corp., 181 U.S.P.Q. 744, 748 (N.D. Ill. 1974). This theory of unenforceability has been termed "infectious unenforceability" by district courts and recognized by the Federal Circuit. See Baxter, 149 F.3d at 1327. It is premised on the guiding principle that "the duty of candor extends through the patent's entire prosecution history," and that a breach of the duty of candor "may render unenforceable all claims which eventually issue from the same or a related application." Fox, 922 F.2d at 803-04. Charges of infectious inequitable conduct are disfavored even more than charges of inequitable conduct. Eaton Corp. v. Parker-Hannifin Corp., 2003 U.S. Dist. LEXIS 1014, *2 (D. Del. Jan. 24, 2003). To prove infectious unenforceability, an accused infringer must establish "inequitable conduct sufficient to hold at least one patent

unenforceable before [a court will] consider[] whether to hold an entire group of related patents unenforceable." Speedplay, Inc. V. Bebop Inc., 211 F.3d 1245, 1259 (Fed. Cir. 2000). If this threshold requirement is met, then the accused infringer must demonstrate an "immediate and necessary relation" between the alleged inequitable conduct and enforcement of the related patents. Ronald A. Katz Tech. Licensing, L.P. v. Verizon Communications Inc., 2002 U.S. Dist. LEXIS 12982, *7-8 (E.D. Pa. July 16, 2002) (internal citations omitted).

The court concludes that Arthocare did not commit inequitable conduct during the prosecution of the '592 patent, during the reexamination of the '536 patent, or in conjunction with the certificate of correction for the '882 patent. Considering the '592 patent, the court notes that the use of electrically conductive fluid is material to the patentability of the '592 invention given that it appears as a limitation in the asserted '592 patent claims. The court does not find that Mr. Raffle, however, intended to deceive the PTO concerning the '198 patent. Smith & Nephew presented no evidence of record to show that Mr. Raffle purposefully misrepresented material facts or submitted false material information about this prior art reference. Rather, the record shows that Mr. Raffle provided this prior art reference to the PTO for consideration during the prosecution of the '592 patent. (See D.I. 428, ex. B at B27)

The examiner was free to reach his own conclusions regarding the teachings contained in this reference.²⁵ (See id. at B23-26) Indeed, the Federal Circuit has opined that an examiner is free to accept or reject an inventor's interpretation of the teachings of a reference. Life Techs., Inc. V. Clontech Labs., Inc., 224 F.3d 1320, 1326 (Fed. Cir. 2000). Mr. Raffle's statements about electrically conductive fluid merely reflected his understanding of the '198 patent.

As to Judge Orrick's opinion, the court concludes yet again that it was not material to the patentability of the '592 patent. The opinion was preliminary in nature since it was issued pursuant to Arthrocare's motion for a preliminary injunction. It likewise did not directly address the anticipatory effects of the '198 patent on the application that was granted as the '592 patent. Rather, Judge Orrick found that the '198 patent raised substantial questions as to the validity of select claims of patents other than the '592 patent, namely, the '536 patent and the '281 patent.

Even assuming, arguendo, that Judge Orrick's opinion was material, Arthrocare complied with its duty of disclosure under the Manual of Patent Examining Procedure ("MPEP") Section 2001.06(c). This section states that

²⁵The examiner ultimately concluded that the '198 patent did not disclose electrically conducting fluid. (See id. at B40-41)

[w]here the subject matter for which a patent is being sought is or has been involved in litigation, the existence of such litigation and any other material information arising therefrom must be brought to the attention of the U.S. Patent and Trademark Office. . . . At a minimum, the applicant should call the attention of the Office to the litigation, the existence and the nature of any allegations relating to validity and/or 'fraud,' or 'inequitable conduct' relating to the original patent, and the nature of litigation material relating to these issues. Enough information should be submitted to clearly inform the Office of the nature of the issues so that the Office can intelligently evaluate the need for asking for further materials in the litigation.

MPEP § 2001.06(c) (2003). Arthocare submitted a list of documents from the Arthocare v. Ethicon, Inc. litigation to the PTO. This list included Judge Orrick's opinion. (See id. at B7, ¶40) The court cannot conclude that Arthocare intended to deceive the PTO concerning Judge Orrick's opinion given its compliance with Section 2001.06(c). Accordingly, the court grants Arthocare's motion for entry of judgment of no inequitable conduct as to the '592 patent and denies Smith & Nephew's cross motion to strike Arthocare's motion for entry of judgment of no inequitable conduct as to the '592 patent.

Turning to the '536 patent, the court finds that Arthocare did not intend to deceive the PTO concerning its suit against Smith & Nephew or conceal Smith & Nephew's primary arguments concerning validity and enforceability. In compliance with Section 2001.06(c), Arthocare notified the PTO about the litigation at bar and presented Smith & Nephew's invalidity

arguments in three separate communications, namely: (1) an Information Disclosure Statement dated October 12, 2001 disclosing Smith & Nephew's primary invalidity and unenforceability arguments; (2) a second Information Disclosure Statement dated June 6, 2002 disclosing Smith & Nephew's June 3, 2002 supplemental invalidity contentions in the form of Smith & Nephew's response to Arthrocare's contention interrogatories; and (3) a third Information Disclosure Statement dated December 19, 2002 attaching Smith & Nephew September 10, 2002 invalidity contentions. (See D.I. 428, ex. B at 76-87; 97-230; 290-341) Although these disclosures did not specifically include the summary judgment motions or expert reports in dispute, such documents were cumulative in nature with Smith & Nephew's invalidity contentions already before the PTO. Rule 56(b) states that "information is material to patentability in a reexamination proceeding when it is not cumulative to information already of record or being made of record in the reexamination proceeding." 37 C.R.F. §1.56 (2004). The Federal Circuit has also held that "[a] reference that is simply cumulative to other references does not meet the threshold of materiality that is predicate to a holding of inequitable conduct." Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1582 (Fed. Cir. 1991) (citing Halliburton Co. v. Schlumberger Tech. Corp., 925 F.2d 1435, 1440 (Fed. Cir. 1991)). In addition, the court notes

that these documents were designated "highly confidential" and were subject to the parties' stipulated protective order. This protective order limited the use of "highly confidential" information to persons or entities "to whom such information is disclosed solely for the purposes of this action, and not for any other action or for any business, patent prosecution, licensing, competitive, or governmental purpose or function, and such information shall not be disclosed to anyone except as provided in this [p]rotective [o]rder." (D.I. 40 at ¶6) The in-house corporate counsel who prosecuted the '536 patent during reexamination (i.e., Mr. Raffle and Mr. Sanjay Bagade), consequently, were not privy to "highly confidential" documents. The court, therefore, reasons that Arthrocare's in-house counsel did not intend to deceive the PTO about Smith & Nephew's summary judgment motions and expert reports because they likely were unaware of the existence of these documents.

As to Arthrocare's "off-the record" conversations with the examiner during the '536 reexamination prior to the first office action,²⁶ there is no evidence of record to suggest that Arthrocare's in-house counsel violated 37 C.R.F. § 1.56 or MPEP § 2281. Interviews about the patentability of claims involved in an ex parte reexamination proceeding ordinarily are not conducted

²⁶The examiner issued the first office action on September 24, 2002.

prior to the first office action. See 37 C.R.F. § 1.56 (2004); see also MPEP § 2281 (2001). However, interviews are "permitted where the examiner initiates the interview for the purpose of providing an amendment to make the claims patentable and the patent owner's role is passive. The patent owner's role . . . is limited to agreeing with the change or not." Id. Additionally, 37 C.R.F. § 1.56 and MPEP § 2281 require the patent holder to file a written statement of the substance of the interview with the PTO. In accordance with these rules, Mr. Bagade submitted a statement on December 19, 2002 to summarize various communications with the examiner. While the exact number of conversations between Arthrocare's in-house counsel and the examiner and the dates of such conversations are not clear from the contents of Mr. Bagade's statement, it is evident that at least one occurred prior to the first office action because Mr. Bagade stated that the examiner contacted him in May 2002. (See D.I. 462, ex. B at 228-230) This interview, nevertheless, was consistent with the requirements of MPEP § 2281. That is, the examiner contacted Mr. Bagade for purposes of discussing an amendment to claim 1 of the '536 patent, and Mr. Bagade responded by not agreeing to the amendment. (See id.)

Even though the court cannot identify with certainty the time frames for the remaining interviews of record, the court concludes that the record does not suggest that Mr. Raffle caused

the examiner to "parrot back, verbatim" the arguments that he made with respect to the '198 patent during the earlier prosecution of the '592 patent as alleged by Smith & Nephew, despite his discussions with the examiner about the '198 patent, the '667 patent, and Judge Orrick's opinion.²⁷ Under patent office rules, a patent examiner is charged with a duty to independently conduct a thorough examination.

On taking up an application for examination or a patent in a reexamination proceeding, the examiner shall make a thorough study thereof and shall make a thorough investigation of the available prior art relating to the subject matter of the claimed invention. The examination shall be complete with respect both to compliance of the application or patent under reexamination with the applicable statutes and rules and to the patentability of the invention as claimed, as well as with respect to matters of form, unless otherwise indicated.

37 C.R.F. §1.104(a)(1) (2004). The Federal Circuit "presumes that the Patent Office complies with its own rules, a presumption overcome only upon presentation of contrary evidence." Genzyme Corp. v. Transkaryotic Therapies, Inc., 346 F.3d 1094, 1103 (Fed. Cir.) (citing Rite Hite Corp. v. Kelley Co., Inc., 819 F.2d 1120, 1123 (Fed. Cir. 1987)). In line with this duty, the examiner placed his initials next to the '198 patent on the Form PTO-1449, indicating that he considered the patent. The examiner confirmed

²⁷Additional communications of record entailed procedural concerns, such as the status of the reexamination proceedings, filing of information disclosure statements, and an estimate of when the PTO would provide the first office action.

this review in a November 15, 2002 office action, stating that he engaged in "careful[] consideration and review of the Roos '198 patent." (PX 7 at 214) Therefore, without evidence of indiscretion during the '536 reexamination proceeding, the court finds that Smith & Nephew's allegations regarding inequitable conduct based on off-the-record conversations to be without merit. Consequently, the court grants Arthrocare's motion for entry of judgment of no inequitable conduct as to the '536 patent and denies Smith & Nephew's cross motion to strike Arthrocare's motion for entry of judgment of no inequitable conduct as to the '536 patent.

Focusing on the '882 patent, the court finds no evidence in the record to substantiate Smith & Nephew's allegations that Mr. Raffle intentionally misled the PTO when he asserted that he amended all claims to replace the term "active electrode" with "electrode terminal" or when he presented an antecedent basis argument as grounds to amend application claim 23 (i.e., issued claim 1) but did not point out other instances of improper antecedent basis within the claim set. Mr. Raffle filed a supplemental amendment during the prosecution of the '882 patent to change "active electrode" to "electrode terminal" and "electrically conducting liquid" to "electrically conducting

fluid."²⁸ (See DTX 306 at C2-C12) He missed one correction of "active electrode" in application claim 23 and one instance of the same correction in application claim 52. Recognizing these mistakes after reviewing the '882 patent on the day it issued, Mr. Raffle filed a request for certificate of correction the following day. (See 1527, DTX 306 at C13-C15) In his request, Mr. Raffle explained that he mistakenly forgot to replace the term "active electrode" with "electrode terminal" in one place in application claim 23 and that such failure potentially created an antecedent basis problem. (See DTX 306 at C13) Given this sequence of events, the court concludes that Mr. Raffle made honest mistakes in amending the claims; he did not craft claims to read on Ethicon's products in order to file an infringement action against Ethicon. The court, consequently, grants Arthrocare's motion for entry of judgment of no inequitable conduct as to the '882 patent and denies Smith & Nephew's cross motion to strike Arthrocare's motion for entry of judgment of no inequitable conduct as to the '882 patent.

Finally, because the court has not found Arthrocare liable for inequitable conduct with respect to any of the individual patents in suit, the court declines to hold them collectively unenforceable based upon an alleged pattern of inequitable

²⁸Mr. Raffle replaced seventeen of the nineteen occurrences of the term "active electrode," including three in application claim 23 and two in application claim 52.

conduct. Even if the court had found just one patent invalid on inequitable conduct grounds, the court is not convinced that Smith & Nephew would be able to show an "immediate and necessary relation" between the inequitable conduct associated with that one patent and the enforcement of the other two patents. To establish the requisite relatedness, Smith & Nephew relies on the fact that the three patents in suit share the same inventors, concern the same electrosurgical system, have been licensed together, and were asserted concurrently in the instant litigation. Nevertheless, this court agrees with the Eastern District of Pennsylvania's holding that "[m]ere relatedness of subject matter' is insufficient to establish this [immediate and necessary] relationship." Id. (citing Consol. Aluminum Corp. v. Foseco Int'l Ltd., 910 F.2d 804, 810-811 (Fed. Cir. 1990)). In cases where courts found infectious unenforceability, there was greater connection between the act that triggered the inequitable conduct finding and the other patents in suit than in the case at bar. For example, in Consol. Aluminum Corp. 910 F.2d 804, the Federal Circuit held that the intentional fabrication of a fictitious best mode in one patent rendered three other patents with intertwined prosecution histories, two of which were continuations-in-part of the third, unenforceable. The court, therefore, grants Arthrocare's motion for entry of judgment of no inequitable conduct and denies Smith & Nephew's cross motion to

strike Arthrocare's motion for entry of judgment of no inequitable conduct on infectious unenforceability grounds.

J. Arthrocare's Motion for a Permanent Injunction

Arthrocare moves for entry of a permanent injunction to enjoin Smith & Nephew from directly infringing, contributing to the infringement, and inducing the infringement of the '536, '592, or '882 patents (1) by making, using, offering to sell, selling, marketing, advertising, or promoting in the United States or importing into the United States all models of the Saphyre, ElectroBlade, and Control RF products until the expiration of the patents in suit; and (2) by instructing, training, or otherwise actively encouraging others in the United States to use all models of the Saphyre, ElectroBlade, and Control RF products until the expiration of the patents in suit. The framers of the Constitution of the United States recognized that a patentee has the right to exclude others from practicing a patented invention. As a result of this belief, the framers adopted Clause 8 of Section 8, Article I which states: "The Congress shall have power . . . to promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." U.S. Const. art. I, § 8. Congress used their power to enact 35 U.S.C. § 283. This provision of law authorizes a court to "grant injunctions in accordance with the

principles of equity to prevent the violation of any right secured by patent, on such terms as the [c]ourt deems reasonable." 35 U.S.C. § 283.

In a patent infringement suit, a district court may grant a preliminary injunction pending trial or a permanent injunction "after a full determination on the merits." High Tech. Med. Instr., Inc. v. New Image Indus., Inc., 49 F.3d 1551, 1554 (Fed. Cir. 1995). Indeed, the Federal Circuit has indicated that once a finding of infringement has been made, then an injunction should issue absent a sufficient reason for denying it. Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1247 (Fed. Cir. 1989). Courts, therefore, are given wide latitude in framing injunctive relief. KSM Fastening Sys., Inc. v. H.A. Jones Co., 776 F.2d 1522, 1527 (Fed. Cir. 1985). Nonetheless, consistent with the equitable nature of a permanent injunction, the court "must consider all circumstances, including the adequacy of the legal remedy, irreparable injury, whether the public interest would be served, and the hardship on the parties and third parties. E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co., 659 F. Supp. 92, 94 (D. Del. 1987). Additionally, Rule 65(d) of the Federal Rules of Civil Procedure requires an injunction to "set forth the reasons for its issuance, be specific in its terms, and shall describe in reasonable detail, and not by reference to the complaint or other document, the act

or acts sought to be restrained; and is binding only upon the parties to the action." Fed. R. Civ. P. 65(d).

In the instant case, the court finds Arthocare will suffer irreparable harm without a permanent injunction to prevent Smith & Nephew from practicing its patented inventions. As best stated by the Federal Circuit in H.H. Robertson Co. v. United Steel Deck, Inc., 820 F.2d 384 (Fed. Cir. 1987):

In matters involving patent rights, irreparable harm has been presumed when a clear showing has been made of patent validity and infringement . . . The nature of the patent grant thus weighs against holding that monetary damages will always suffice to make the patentee whole, for the principal value of a patent is its statutory right to exclude.

Id. at 390.

Additionally, the public interest in preserving incentives to advance science and useful arts favors entry of an injunction to bar any further infringement by Smith & Nephew. The court recognizes that intellectual property law is premised on the desire to give inventors an incentive to invent and to reap the benefits of their labor. To this end, the Federal Circuit has previously noted that

[o]ne of those benefits is the right to prevent others from practicing what they have invented. Otherwise, if inventors cannot depend on their patents to exclude others, we fear that research and development budgets in the science and technology based industries would shrink, resulting in the public no longer benefitting from the labors of these talented people.

E.I. DuPont de Nemours v. Polaroid Graphics Imaging, Inc., 706 F. Supp. 1135, 1146 (D. Del. 1989). Under the facts at bar, Arthrocare created the market for electrosurgery probes by launching its first bipolar radio frequency ablation product for arthroscopic surgery in 1995. (See PX 450 at 3) Smith & Nephew later joined this market. (See PX 593 at 24, 39)

Finally, the court notes that removing the Saphyre, ElectroBlade, and Control RF probes from the stream of commerce will not harm or cause hardship to the public since Arthrocare, along with several other suppliers like Mitek and Stryker, offer alternative viable probes. As well, Smith & Nephew has already pulled the Control RF product from the market and only just recently launched the ElectroBlade and Saphyre products. The fact that Smith & Nephew may suffer a loss in revenue is not of concern. Indeed, the Federal Circuit has commented that just because an injunction might put an infringer out of business does not justify denying it. See Windsurfing Int'l, Inc. v. AMF, Inc., 782 F.2d 995, 1003 (Fed. Cir. 1986). "One who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." Id. Therefore, concluding that all relevant factors weigh in favor of granting a permanent

injunction, the court grants Arthrocare's motion for a permanent injunction.²⁹

V. CONCLUSION

For the reasons stated, the court denies Smith & Nephew's motion for judgment as a matter of law, motion for a new trial, and motion to strike Arthrocare's motion for entry of judgment of no inequitable conduct. The court also denies Smith & Nephew's motion to modify the protective order. The court grants Arthrocare's motion for entry of judgment of no inequitable conduct and motion for entry of a permanent injunction. An order shall issue.

²⁹The court notes that Smith & Nephew's antitrust counterclaims are no longer pending before the court and will not be adjudicated in phase two. The court granted Arthrocare's motion to dismiss Smith & Nephew's antitrust counterclaims in a separately issued memorandum opinion. For this reason, the court concludes that it is not premature to issue a permanent injunction at this time.

(484)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

O R D E R

At Wilmington, this ~~10th~~ day of March, 2004, consistent with
the memorandum opinion issued this same day;

IT IS ORDERED that:

1. Smith & Nephew's motion for judgment as a matter of law pursuant to Rule 50(b) is denied. (D.I. 458)
2. Smith & Nephew's motion for a new trial pursuant to Rule 59 is denied. (D.I. 455)
3. Arthrocare's motion for entry of judgment of no inequitable conduct is granted. (D.I. 427)
4. Smith & Nephew's cross motion to strike Arthrocare's motion for entry of judgment of no inequitable conduct is denied. (D.I. 437)
5. Arthrocare's motion for a permanent injunction is granted. (D.I. 424)

6. Smith & Nephew's motion to modify the protective order
is denied as moot. (D.I. 432)

Sheila L. Robner
United States District Judge

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

Jack B. Blumenfeld, Esquire, Karen Jacobs Loudon, Esquire and James W. Parrett, Jr., Esquire of Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware. Counsel for Plaintiff. Of Counsel: Matthew D. Powers, Esquire, Jared Bobrow, Esquire and Perry Clark, Esquire of Weil, Gotshal & Manges LLP, Redwood Shores, California.

William J. Marsden, Jr., Esquire and Keith A. Walter, Jr., Esquire of Fish & Richardson P.C., Wilmington, Delaware. Counsel for Defendant. Of Counsel: Mark J. Hebert, Esquire and Kurtis D. MacFerrin, Esquire of Fish & Richardson P.C., Boston, Massachusetts.

MEMORANDUM OPINION

Dated: March 10, 2004
Wilmington, Delaware


ROBINSON, Chief Judge

I. INTRODUCTION

On July 25, 2001, plaintiff Arthrocare Corporation ("Arthrocare") filed this action against defendant Smith & Nephew, Inc. ("Smith & Nephew") alleging willful infringement of certain claims of U.S. Patent Nos. 5,697,536 (the "'536 patent"), 5,697,882 (the "'882 patent") and 6,224,592 (the "'592 patent") directed to electrosurgery devices and methods. (D.I. 1) Smith & Nephew answered the complaint on September 13, 2001 denying the infringement allegations and asserting five affirmative defenses including noninfringement, invalidity, misuse, unenforceability based upon inequitable conduct, and unclean hands. (D.I. 10) Smith & Nephew also asserted counterclaims for declaratory judgment that the patents in suit are invalid and not infringed by any act of Smith & Nephew and that the '592 patent is unenforceable due to inequitable conduct. (D.I. 10) On September 26, 2001, Arthrocare denied Smith & Nephew's counterclaims. (D.I. 20) With the court's permission, Smith & Nephew amended their answer on November 27, 2002 to add counterclaims for antitrust violations under 15 U.S.C. § 1 of the Sherman Act. (D.I. 219) Specifically, Smith & Nephew alleges that Arthrocare and Ethicon, Inc. violated antitrust law by bringing and maintaining the instant action to restrain trade "knowing the '536, '882, and/or '592 patents are invalid,

unenforceable, and/or not infringed by any act of Smith & Nephew." (D.I. 219 at ¶27-37)

ArthroCare is organized under the laws of the State of Delaware with its principal place of business in California. (D.I. 1 at ¶2) Smith & Nephew is also organized under the laws of State of Delaware with its principal place of business in Massachusetts. (D.I. 1 at ¶3) Smith & Nephew manufactures and sells the following three allegedly infringing products: the Saphyre bipolar ablation probe ("Saphyre"), the Dyonics Control RF System ("Control RF"), and the ElectroBlade Resector ("ElectroBlade"). The court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331, 1338(a) and 2201(a).

The court separated the issues raised by the parties into two phases pursuant to Smith & Nephew's motion to bifurcate the issues of willfulness and damages until a jury verdict on infringement and validity of the patents in suit. (See D.I. 206) The first phase, in turn, included the issues of infringement, validity, and inequitable conduct ("the patent litigation"). The parties tried these issues before a jury from April 30, 2003 through May 9, 2003. On May 12, 2003, the jury returned a verdict in favor of Arthrocare on all issues. (See D.I. 405) That is, the jury found that Smith & Nephew directly infringed, induced infringement, and contributed to the infringement of the following claims of the three patents in suit with its Saphyre,

ElectroBlade, and Control RF products: claims 46, 47, and 56 of the '536 patent, claims 13, 17, and 54 of the '882 patent, and claims 1, 3, 4, 11, 21, 23, 26, 27, 32, and 42 of the '592 patent. (See id.) The jury also found that none of the patents were invalid on anticipation or lack of enablement grounds. (See id.)

The second phase is presently pending before the court and includes the issues of willfulness, damages, and Smith & Nephew's antitrust counterclaims. Currently before the court is Arthrocare's motion to dismiss Smith & Nephew's antitrust counterclaims.¹ (D.I. 429) For the reasons that follow, the court grants said motion.

II. BACKGROUND

Arthrocare filed suit against Ethicon, Inc., Mitek Surgical Products, Inc., and Gynecare, Inc. in the Northern District of California on February 13, 1998, alleging infringement of eight claims in four patents. (Arthrocare Corp. v. Ethicon, Inc., No. C-98-0609 WHO (N.D. Cal. Dec. 1, 1998); D.I. 321, ex. A at 1) The claims at issue included: (1) claims 40 and 44 of United States Patent No. 5,697,909 ("the '909 patent"); (2) claim 45 of

¹Arthrocare filed this motion to dismiss on May 27, 2003. Smith & Nephew has not responded, despite mentioning its antitrust counterclaims in its answering brief opposing Arthrocare's motion for a permanent injunction in the patent litigation filed with the court on June 4, 2003. (See D.I. 436) The court, therefore, presumes that Smith & Nephew does not oppose the motion.

the '536 patent; (3) claim 101 of United States Patent No. 5,697, 281 ("the '281 patent); and (4) claims 1, 26, 28, and 32 of the '882 patent. (Id. at 2) On March 10, 1998, Arthrocare moved for a preliminary injunction against Ethicon and Mitek to enjoin the two from making, using, importing, selling, or offering for sale an electrosurgery system marketed and sold under the VAPR System name. (Id.) Senior Judge William H. Orrick issued a memorandum decision on December 1, 1998 denying Arthrocare's preliminary injunction motion. (Id. at 33) Judge Orrick found that the defendants raised substantial questions as to (1) whether claims 40 and 44 of the '909 patent and claims 26 and 28 of the '882 patent are invalid for obviousness; (2) whether claim 45 of the '536 patent and claim 101 of the '281 patent are invalid for anticipation and obviousness; and (3) whether claims 1 and 32 of the '882 patent are invalid for lack of enablement. (Id.) The parties settled the litigation in June 1999 prior to trial.

III. STANDARD OF REVIEW

Rule 12(b)(6) of the Federal Rules of Civil Procedure permits a court to dismiss a complaint for failure to state a claim upon which relief can be granted. The purpose of a motion to dismiss is to test the sufficiency of a complaint, not to resolve disputed facts or decide the merits of the case. Kost v. Kozakiewicz, 1 F.3d 176, 183 (3d Cir. 1993). In analyzing a motion to dismiss under this rule, the court, therefore, must

accept as true all material allegations of the complaint and it must construe the complaint in favor of the plaintiff. See Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts, Inc., 140 F.3d 478, 483 (3d Cir. 1998). The court, however, is not required to credit "bald assertions" or "legal conclusions." Morse v. Lower Merion Sch. Dist., 132 F.3d 902, 906 (3d Cir. 1997). "A complaint should be dismissed only if, after accepting as true all of the facts alleged in the complaint, and drawing all reasonable inferences in the plaintiff's favor, no relief could be granted under any set of facts consistent with the allegations of the complaint." Id. The defendant has the burden of persuasion to show that no claim has been stated. See Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991).

IV. DISCUSSION

Smith & Nephew's antitrust counterclaims are premised on the idea that Arthrocare and Ethicon filed "sham" litigation against Smith & Nephew to prevent or to restrain it from entering the arthroscopic surgery market.² Smith & Nephew appears to base this allegation on Judge Orrick's ruling that there were substantial questions concerning the validity of the '882 and '536 patents. In fact, Smith & Nephew particularly asserts that

²Arthrocare and Ethicon have a combined seventy-five percent share of the market in the United States for arthroscopic surgical devices. (D.I. 219 at ¶35)

the "patent infringement action is objectively baseless in that no reasonable litigant could realistically expect success on the merits." (D.I. 219 at 136) Arthrocare argues in rebuttal that the jury's verdict in its favor on infringement and invalidity proves that the patent litigation was not a "sham."

A party who petitions the government for redress generally is immune from antitrust liability. Eastern R.R. Presidents Conference v. Noerr Motor Freight, 365 U.S. 127 (1961); United Mine Workers of Am. v. Pennington, 381 U.S. 657 (1965). Commonly referred to as the Noerr-Pennington doctrine, this immunity extends to persons who petition all types of government entities, including legislatures, administrative agencies, and courts. California Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 510 (1972). Although originally developed in the antitrust context, courts have applied this doctrine universally to business torts. See Cheminor Drugs, Ltd. v. Ethyl Corp., 168 F.3d 119, 128-29 (3d Cir. 1999) (applying the doctrine to common law claims of malicious prosecution, tortious interference with contract, tortious interference with prospective economic advantage, and unfair competition); see also IGEN Int'l, Inc. v. Roche Diagnostics GmbH, 335 F.3d 303, 310 (4th Cir. 2003). Noerr-Pennington immunity, however, is subject to an exception for "sham" litigation. The Supreme Court has held that Noerr-Pennington immunity does not apply to petitions that are a

"mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." Noerr, 365 U.S. at 144. In this regard, the Supreme Court outlined a two-part definition for the term "sham litigation." Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49 (1993). As an objective first part, "the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." Id. at 60. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, then the suit does not qualify as sham litigation and is immunized under the Noerr-Pennington doctrine. Id. In other words, the antitrust claim premised on the sham exception must fail. The subjective second part of the definition arises only if the challenged litigation is objectively meritless. In such case, the court must decide whether the "baseless lawsuit conceals 'an attempt to interfere directly with the business relationships of a competitor.'" Id. at 60-1.

The court disagrees with Smith & Nephew and finds that Arthrocare instituted the patent litigation in a legitimate attempt to protect its patented inventions. The court rejects the notion that Judge Orrick's decision undermined Arthrocare's belief that its patents were valid, enforceable, and infringed by Smith & Nephew's Saphyre, ElectroBlade, and Control RF probes.

Judge Orrick's opinion was based upon a partially developed record and was issued in response to Arthrocare's motion for a preliminary injunction. Under 35 U.S.C. § 282, a patent is presumed valid, and invalidity may be established only by clear and convincing evidence. See 35 U.S.C. § 282 (2003). Such is not the standard employed in a preliminary injunction proceeding.

Additionally, the court notes that in Applera Corp. V. Micromass UK Ltd., 204 F. Supp.2d 724, 782 (D. Del. 2002), antitrust counterclaims like those at bar were dismissed after a jury verdict of infringement and validity, based upon the reasoning that a jury verdict in plaintiff's favor proved the litigation had merit. Applying this reasoning to the instant case, the court likewise concludes that the objective threshold for "sham" litigation is not satisfied and that the Noerr-Pennington doctrine shields Arthrocare from liability for Smith & Nephew's antitrust counterclaims. Accordingly, the court grants Arthrocare's motion to dismiss Smith & Nephew's counterclaims.

V. CONCLUSION

For the reasons stated, the court grants Arthrocare's motions to dismiss Smith & Nephew's antitrust counterclaims. An order shall issue.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.,

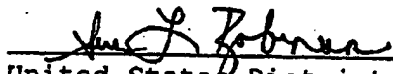
Defendant.

Civ. No. 01-504-SLR

O R D E R

At Wilmington, this 10th day of March, 2004, consistent with
the memorandum opinion issued this same day;

IT IS ORDERED that Arthrocare's motion to dismiss Smith &
Nephew's antitrust counterclaims is granted. (D.I. 429)


United States District Judge

504

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.,

Defendant.

Civ. No. 01-504-SLR

SMITH & NEPHEW, INC.,

Counterclaim Plaintiff,

v.

ARTHROCARE CORPORATION and
ETHICON, INC.,

Counterclaim Defendants.

REVISED ORDER

At Wilmington this ~~17~~²¹ day of April, 2004, consistent
with the memorandum opinion issued on March 10, 2004;

IT IS ORDERED that:

1. Plaintiff's motion to dismiss defendant's antitrust
counterclaims (D.I. 429) is granted.

2. Defendant/counterclaim plaintiff's antitrust

counterclaims are dismissed as to all counterclaim defendants.


United States District Judge

1501

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

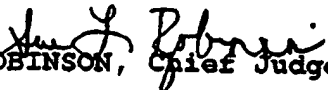
ARTHROCARE CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

Jack B. Blumenfeld, Esquire, Karen Jacobs Loudon, Esquire and James W. Parrett, Jr., Esquire of Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware. Counsel for Plaintiff. Of Counsel: Matthew D. Powers, Esquire, Jared Bobrow, Esquire and Perry Clark, Esquire of Weil, Gotshal & Manges LLP, Redwood Shores, California.

William J. Marsden, Jr., Esquire and Keith A. Walter, Jr., Esquire of Fish & Richardson P.C., Wilmington, Delaware. Counsel for Defendant. Of Counsel: Mark J. Hebert, Esquire and Kurtis D. MacFerrin, Esquire of Fish & Richardson P.C., Boston, Massachusetts.

MEMORANDUM OPINION

Dated: April 21, 2004
Wilmington, Delaware


ROBINSON, Chief Judge

I. INTRODUCTION

On July 25, 2001, plaintiff Arthrocare Corporation ("Arthrocare") filed this action against defendant Smith & Nephew, Inc. ("Smith & Nephew") alleging willful direct, contributory, and inducing infringement of certain claims of U.S. Patent Nos. 5,697,536 (the "'536 patent"), 5,697,882 (the "'882 patent") and 6,224,592 (the "'592 patent"). (D.I. 1) Smith & Nephew answered the complaint on September 13, 2001 denying the infringement allegations and asserting five affirmative defenses including noninfringement, invalidity, misuse, unenforceability based upon inequitable conduct, and unclean hands. (*Id.*) Smith & Nephew also asserted counterclaims for a declaratory judgment that the patents in suit are invalid and not infringed by any act of Smith & Nephew and that the '592 patent is unenforceable due to inequitable conduct. (D.I. 10) On September 26, 2001, Arthrocare denied Smith & Nephew's counterclaims. (D.I. 20) With the court's permission, Smith & Nephew amended its answer on November 27, 2002 to add counterclaims for antitrust violations under 15 U.S.C. § 1 of the Sherman Act. (D.I. 219) By order dated November 27, 2002, the court stayed discovery and trial related to the antitrust counterclaims. (D.I. 206)

From April 30, 2003 through May 9, 2003, the

parties tried the issues of infringement and invalidity before a jury. The jury found by a preponderance of the evidence that Smith & Nephew directly infringed, induced infringement, and contributed to the infringement of claims 46, 47, and 56 of the '536 patent with its Saphyre, ElectroBlade, and Control RF products. (D.I. 405) The jury also found by a preponderance of the evidence that Smith & Nephew induced infringement and contributed to the infringement of claims 13, 17, and 54 of the '882 patent with its Saphyre, Saphyre with Suction, and Control RF products. (Id.) In addition, the jury found by a preponderance of the evidence that Smith & Nephew induced infringement and contributed to the infringement of claims 1, 3, 4, 11, 21, 23, 26, 27, 32, and 42 of the '592 patent with its Saphyre, ElectroBlade, and Control RF products.¹ (Id.) The jury further found that Smith & Nephew did not prove by clear and convincing evidence that the patents in suit are invalid. (Id.)

Following this verdict, the parties filed numerous post-trial motions. Smith & Nephew, in particular, challenged every issue that the jury decided and also nearly every issue that the court decided. The court issued a memorandum opinion and order on March 10, 2004 addressing these motions. (See D.I.

¹The jury was not asked to decide whether Smith & Nephew contributed to the infringement or induced the infringement of claims 21 and 42 of the '592 patent with its Saphyre or ElectroBlade products.

483, 484) The court found that the jury based their decisions as to infringement and invalidity upon substantial evidence and upheld the jury verdict. The court granted Arthrocare's motion for a permanent injunction pursuant to the findings of infringement.

Presently before the court are Smith & Nephew's motion for reconsideration of orders granting Arthrocare's motion for a permanent injunction and Smith & Nephew's motion to stay the injunction or, alternatively, to grant a transition period. For the reasons that follow, the court denies the motion for reconsideration, denies the motion to stay in part as to the stay per se, and grants the motion to stay in part to allow for a three month transition period.

II. DISCUSSION

A. Smith & Nephew's Motion for Reconsideration of Orders Granting Arthrocare's Motion for a Permanent Injunction²

"As a general rule, motions for reconsideration should be granted 'sparingly.'" Stafford v. Noramco of Delaware, Inc., 2001 WL 65738, *1 (D. Del. 2001) (quoting Karr v. Castle, 768 F.

²Because the court dismissed Smith & Nephew's antitrust counterclaim, the court concluded that it was not premature to enter a permanent injunction in favor of Arthrocare. (D.I. 483 at 90, n.29) Thus, Smith & Nephew's instant motion is inextricably tied to the motion to dismiss. The court, therefore, necessarily must address its decision to dismiss the antitrust counterclaims in the context of the instant motion for reconsideration.

Supp. 1087, 1090 (D. Del. 1991)). The purpose of granting a motion for reconsideration is to "correct manifest errors of law or fact or to present newly discovered evidence." Harsco Corp. v. Zlotnicky, 176 F.3d 669, 677 (3d Cir. 1999) (citing Keene Corp. v. International Fid. Ins. Co., 561 F. Supp. 656, 665 (N.D. Ill. 1983)). Parties, therefore, should remain mindful that a motion for reconsideration is not merely an opportunity to "accomplish repetition of arguments that were or should have been presented to the court previously." Karr v. Castle, 768 F. Supp. 1087, 1093 (D. Del. 1991) (citing Brambles U.S.A., Inc. v. Blocker, 735 F. Supp. 1239, 1240-41 (D. Del. 1990)). A court should reconsider a prior decision if it overlooked facts or precedent that reasonably would have altered the result. Id. (citing Weissman v. Fruchtman, 124 F.R.D. 559, 560 (S.D.N.Y. 1989)).

Smith & Nephew complains that the court, in granting Arthrocare's motion to dismiss its antitrust counterclaim, relied on two mistaken assumptions: (1) that Arthrocare's motion to dismiss was unopposed; and (2) that the viability of Smith & Nephew's antitrust counterclaim depends on a showing that the antitrust action was objectively baseless "sham" litigation. Smith & Nephew argues that it did not respond to the motion to dismiss because the court specifically stayed the antitrust counterclaim pending resolution of the patent issues during a teleconference with the parties on June 9, 2003.

As a result, Smith & Nephew asserts that its intent to oppose the motion to dismiss coupled with the court's orders staying the issue presents sufficient grounds for reconsideration.

The court disagrees. As noted above, on November 27, 2002, the court issued a memorandum order staying **discovery** and **trial** of Smith & Nephew's antitrust counterclaim. (D.I. 206) The court reviewed this order in deciding the motion to dismiss and concluded that said stay did not impact the motion to dismiss for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6). Arthrocare filed this motion in lieu of an answer to Smith & Nephew's antitrust counterclaims. As such, the court simply addressed the sufficiency of Smith & Nephew's counterclaim; it did not resolve disputed facts or decide the merits of Smith & Nephew's antitrust case. Therefore, the court acted consistent with its prior rulings.³

More importantly, the court decided said motion based upon the correct law. The court noted in its memorandum opinion that "[t]he Supreme Court has held that Noerr-Pennington immunity does not apply to petitions that are a 'mere sham to cover what is

³Smith & Nephew's reliance on one statement from a June 2003 teleconference is misplaced. The court notes in this regard that the instant docket consists of hundreds of entries, including a dozen transcripts from telephone conferences. The court has had to resolve fifty-one substantive motions in this case, which is only one of sixty-six patent cases on the court's docket. If Smith & Nephew believed that Arthrocare's motion was premature and inconsistent with the court's prior rulings, it should have indicated so in a timely manner.

actually nothing more than an attempt to interfere directly with the business relationships of a competitor.'" (D.I. 481 at 6-7) The court applied this holding and concluded that "the objective threshold for 'sham' litigation is not satisfied and that the Noerr-Pennington doctrine shields Arthrocare from liability for Smith & Nephew's antitrust counterclaims." (Id. at 8) The court is not persuaded that any argument from Smith & Nephew about the basis for its antitrust allegations will change the court's decision. Accordingly, because the court is convinced that it properly decided the motion to dismiss, the court denies Smith & Nephew's motion for reconsideration of orders granting Arthrocare's motion for a permanent injunction.

B. Smith & Nephew's Motion to Stay the Permanent Injunction Or, Alternatively, to Grant a Transition Period

Smith & Nephew seeks a stay of the permanent injunction pending appeal to avoid injustice or, in the alternative, a six to twelve month transition period to allow the medical community to switch to alternative products. A court may stay an injunction pending appeal pursuant to Federal Rule of Civil Procedure 62(c). In exercising its discretion to issue such a stay, the Federal Circuit has indicated that a court must consider four factors: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay;

(3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." Standard Havens Prods. v. Gencor Indus., 897 F.2d 511, 512 (Fed. Cir. 1990) (citations omitted). The Federal Circuit also has opined that each factor need not be given equal weight. Id. at 513. Instead, a court should use a flexible balancing approach.

Applying these considerations to Smith & Nephew's assertion that it is entitled to a stay pending appeal, the court finds that Smith & Nephew has not established any of Standard Havens factors sufficient to warrant a stay. First, there is no convincing evidence that Smith & Nephew's appeal carries a strong likelihood of success on the merits. Smith & Nephew argues that the ultimate validity of the asserted patents is in substantial doubt given that the United States Patent & Trademark Office ("PTO") has granted its requests for reexamination of each of the asserted patents, finding "substantial new questions of patentability." A reexamination proceeding, however, is different from litigation. Indeed, the Federal Circuit has recognized that "litigation and reexamination are distinct proceedings, with distinct parties, purposes, procedures, and outcomes."⁴ Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1427 (Fed.

⁴The Federal Circuit explained the distinctions between the two proceedings succinctly as follows:

Before the courts, a patent is presumed valid and the

Cir. 1988) (citing In re Etter, 756 F.2d 852, 857 (Fed. Cir. 1985)). To this end, "[t]he two forums take different approaches in determining invalidity and on the same evidence could quite correctly come to different conclusions. . . . And, if the district court determines a patent is not invalid, the PTO should continue its reexamination because, of course, the two forums have different standards of proof for determining validity." Id. at 1428-29. In light of these differences, the court is not persuaded that the ongoing reexamination proceeding triggers a stay of the injunction. A jury has decided the validity of the patents in suit after careful deliberation following a nine day jury trial. This court reviewed the jury's verdict pursuant to post-trial motions and found that the jury based its decision on substantial evidence. Thus, the court has no reason to believe

party asserting invalidity must prove the facts to establish invalidity of each claim by clear and convincing evidence. . . . In a reexamination proceeding, on the other hand, there is no presumption of validity and the "focus" of the reexamination returns essentially to that present in an initial examination, . . . at which a preponderance of the evidence must show nonpatentability before the PTO may reject the claims of a patent application. . . . The intent underlying reexamination is to 'start over' in the PTO with respect to the limited examination areas involved, and to re-examine the claims, and to examine new or amended claims, as they would have been considered if they had been originally examined in light of all of the prior art of record in the reexamination proceeding.

Id. (citations and quotations omitted).

that Smith & Nephew will be successful on its appeal such that the court presently should issue a stay.

Smith & Nephew also asserts that there are substantial claim construction issues on appeal that will require further action by the court.⁵ Smith & Nephew reminds the court that "the Federal Circuit conducts a de novo review of claim construction, and quite frequently reverses or at least modifies the construction applied by the [d]istrict [c]ourt." (D.I. 487 at 11) Nevertheless, as counsel for Smith & Nephew is aware, the court previously has held that the "possibility of appellate de novo review of its claim construction does not constitute an extraordinary circumstance to merit a stay." Eaton Corp. v. Parker-Hannifin Corp., 292 F. Supp. 2d 555, 582 (D. Del. 2003); see Tristrata Tech., Inc. v. ICN Pharms., Inc., 2004 WL 856595, *2 (D. Del. 2004).

Smith & Nephew further contends that it will appeal the fact that the jury was allowed to decide the validity of the Certificate of Correction for the '882 patent. Smith & Nephew maintains that such procedure was contrary to the steps outlined in Superior Fireplace v. Majestic Prods., 270 F.3d 1358 (Fed. Cir. 2001). Smith & Nephew, therefore, avers that it has a

⁵Smith & Nephew particularly challenges the court's claim construction of the "not in contact" limitation in the '592 patent and the "connector" limitation of the '536 patent.

reasonable likelihood of succeeding on this claim.⁶ This assertion is little more than conclusory attorney argument. Moreover, the court agreed with the jury verdict that the certificate of correction is valid. Therefore, even if it was improper to submit this decision to the jury, the court ultimately decided the very issue at the heart of Smith & Nephew's complaint. Accordingly, the court concludes that the first factor weighs against the issuance of a stay.

Second, Smith & Nephew argues that it will be irreparably harmed if a stay is not granted because it will be unable to recover a position in the market. In this regard, Smith & Nephew claims that its ElectroBlade and Saphyre probes are the result of twenty-seven years and millions of dollars in research and development efforts. This argument is a warmed-over version of Smith & Nephew's prior contentions made in opposition to Arthrocare's motion for a permanent injunction. As the patentee, Arthrocare presumptively has suffered irreparable harm throughout the duration of Smith & Nephew's infringing activities. Smith & Nephew cannot now attempt to turn the table and argue that it will suffer harm for continuing to engage in infringement. Such contention offends the very rights associated with obtaining a patent. Additionally, the only harm that Smith

⁶Absent a finding of validity of the Certificate of Correction, Smith & Nephew would not be liable for infringement of the '882 patent.

& Nephew will suffer with any certainty is the loss of profits from the sale of its ElectroBlade and Saphyre probes.⁷ Smith & Nephew has failed to show that any of its employees will lose their jobs, despite alleging that its employees derive their livelihood from the manufacture and sale of the infringing products. As the court originally stated in deciding the parties' post-trial motions, "one who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." Windsurfing Int'l, Inc. v. AMF, Inc., 782 F.2d 995, 1003 (Fed. Cir. 1986); see also E.I. DuPont De Nemours & Co., v. Phillips Petroleum Co., 659 F. Supp. 92, 94-95 (D. Del. 1987) (stating "the loss of customers or business built upon the sale and use of infringing products does not amount, in the context of a patent infringement suit, to irreparable harm from which [the defendant] should be shielded). The court, consequently, concludes that the second factor weighs against the issuance of a stay.

Third, Smith & Nephew claims that Arthrocare's pattern of licensing demonstrates that monetary damages will adequately compensate Arthrocare for its continued infringement during the

⁷Smith & Nephew reported revenue of almost two billion in 2003. (D.I. 487 at 16 n.5) From the infringing products alone, Smith & Nephew generated six million in sales before trial and approximately 7.5 million since the jury verdict. (See D.I. 418 at 869; D.I. 491 at 18)

appeals process. This argument is unpersuasive. Staying the injunction during the appeals process would essentially allow Smith & Nephew to continue to infringe, thereby further usurping the exclusivity that Arthrocare is entitled to enjoy as a result of its patents. Such exclusivity underlies the patent system in the United States. Moreover, Arthrocare's patent rights are not compromised simply because it opted to license its patents to select competitors. "Once the patentee's patents have been held to be valid and infringed, he should be entitled to the full enjoyment and protection of his patent rights." Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1581 (Fed. Cir. 1983).

Furthermore, if Smith & Nephew continues to sell its infringing products, Arthrocare likely will lose market share, profits, and goodwill. Smith & Nephew, in fact, has implemented a specific program within its sales force to convert Arthrocare's customers to using Smith & Nephew products. (See D.I. 491, ex. A) The Federal Circuit has observed that "because the principal value of a patent is its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole." Hybritech, Inc. v. Abbott Labs., 849 F.2d 1446, 1456-57 (Fed. Cir. 1988). As well, "[i]f monetary relief were the sole relief afforded by the patent statute then injunctions would be unnecessary and infringers could become compulsory licensees for as long as the

litigation lasts." Atlas Powder Co. v. Ireco Chems., 773 F.2d 1230, 1233 (Fed. Cir. 1985). In light of the foregoing, the court concludes that the third factor weighs against the issuance of a stay.

Finally, Smith & Nephew charges that an injunction would adversely affect surgeons and their patients. Smith & Nephew specifically claims that denying a stay will deprive surgeons in the United States of their choice of surgical instruments, especially given that the infringing products offer unique features and medical advantages not available in other products.⁸ Nonetheless, the court does not find a stay warranted simply because the litigation at bar involves medical devices as opposed to some other technology that does not relate to issues of human health.⁹ While the court appreciates that select surgeons like Dr. Roy A. Majors and Dr. Gary S. Fanton, both of

⁸The ElectroBlade combines a mechanical shaver with an RF coagulation device, thereby allowing surgeons to resect soft tissue, coagulate bleeders, and continue resecting with a single instrument. The Saphyre utilizes a CoolBack feature, which prevents contact between the return electrode and non-target tissue.

⁹The court notes that Smith & Nephew attempts to mislead it into believing such to be the case in the District of Delaware by its characterization of C.R. Bard, Inc. v. Medtronic, Inc., 1999 WL 458305 (D. Del. 1999). Smith & Nephew suggests that the court stayed an injunction pending appeal because the technology involved arterial filters. (See D.I. 487 at 17) In truth, the court stayed the injunction because the jury's verdict rested on a close question of law concerning the doctrine of equivalents. Id. at 15.

whom submitted declarations on behalf of Smith & Nephew, rely on the unique features offered by the ElectroBlade and Saphyre products, the court finds that reasonable alternative probes exist in the market. As mentioned previously in the court's post-trial memorandum opinion, ArthroCare, Mitek, and Stryker offer probes for use in arthroscopic surgery. The court has no reason to believe that these probes will pose medical risks to patients. Surgeons in the United States, therefore, may utilize them in place of the ElectroBlade and Saphyre probes, albeit after instruction and training. Consequently, the court finds that the fourth factor weighs against the issuance of a stay.

In sum, since all four of the Stanford Havens factors weigh against the issuance of a stay, the court concludes that a stay pending appeal is not justified. Accordingly, the court denies Smith & Nephew's motion to stay the injunction.

With regard to a transition period, the court disagrees with Smith & Nephew that the medical community may need six to twelve months to effect an efficient and orderly transition. The jury returned its verdict of infringement on May 12, 2003. Smith & Nephew, nevertheless, continued to sell and presently still sells the ElectroBlade and Saphyre probes.¹⁰

¹⁰Smith & Nephew stated that in the past year surgeons treated 50,000 patients at 900 hospitals and surgery centers and 200 sales representative spent approximately \$1,100,000 training surgeons and hospital staff to uses its probes. (See D.I. 487 at 17)

Smith & Nephew could have utilized the time between the jury verdict and present to implement the transition it now requests. What is more, a lengthy transition of six to twelve months will cause further irreparable harm to Arthrocare. Notwithstanding this, the court finds that a short transition period of three months is appropriate to allow Smith & Nephew time to alert surgeons not to utilize its probes. This period will also permit the surgeons who rely on Smith & Nephew products to receive instruction and switch to alternative probes. During this time, Smith & Nephew shall not sell any additional infringing probes from its inventory. If Arthrocare becomes aware of such sales by Smith & Nephew, then Arthrocare may immediately notify the court.

III. CONCLUSION

The court denies Smith & Nephew's motion for reconsideration of orders granting Arthrocare's motion for a permanent injunction. The court also denies Smith & Nephew's motion to stay in part as to the stay per se and grants said motion in part to allow for a three month transition period. An order shall issue.

(579)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

REVISED ORDER*

At Wilmington this ~~28~~²⁹ day of April, 2004, consistent with the memorandum opinion issued this same date;

IT IS ORDERED that:

1. Smith & Nephew's motion for reconsideration of orders granting Arthrocare's motion for a permanent injunction (D.I. 488*) is denied.

2. Smith & Nephew's motion to stay or alternatively, to grant a transition period (D.I. 486) is denied in part as to the stay and granted in part to allow for a three month transition period.


United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

AMENDED ORDER

At Wilmington this ~~9th~~ day of June, 2004, having conferred with counsel and having reviewed the papers submitted by the parties;¹

Upon entry, this Amended Order shall replace and supercede the Order entered by this Court on June 9, 2004 (D.I. 522):

IT IS ORDERED that, with respect to the U.S. Patent No. 5,697,536 ("the '536 patent"):

1. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from:

(a) directly infringing claims 46, 47, and 56 of the '536 patent until the expiration of the '536 patent by making, using, offering to sell, or selling in the United States, or importing

¹Arthrocare's motion for entry of a permanent injunction (D.I. 485) is granted, and Smith & Nephew's motion to delay entry of injunction pending consideration of motion to stay injunction in Federal Circuit (D.I. 511) is denied as moot.

into the United States, the Saphyre,² ElectroBlade, or Control RF products listed on Exhibit A attached hereto; (b) inducing the infringement of claims 46, 47, and 56 of the '536 patent until the expiration of the '536 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A ; and (c) contributing to the infringement of claims 46, 47, and 56 of the '536 patent until the expiration of the '536 patent by offering to sell or selling in the United States, or importing into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A.

IT IS FURTHER ORDERED that, with respect to United States Patent No. 5,697,882 ("the '882 patent"):

1. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 13 and 17 of the '882 patent until the expiration of the '882 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the non-suction models of the Saphyre products listed on Exhibit A.

²When the court refers to the Saphyre products listed on Exhibit A herein, the court intends to include both the suction and non-suction models, unless otherwise specified.

2. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 13, 17, and 54 (to the extent it depends from claim 1) of the '882 patent until the expiration of the '882 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the suction models of Saphyre products listed on Exhibit A.

3. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 17 and 54 (to the extent it depends from claim 1) of the '882 patent until the expiration of the '882 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Control RF products listed on Exhibit A.

4. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 13 and 17 of the '882 patent until the expiration of the '882 patent by offering to sell or selling in the United States, or importing into the United States, the non-suction models of the Saphyre products

listed on Exhibit A.

5. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 13, 17, and 54 (to the extent it depends from claim 1) of the '882 patent until the expiration of the '882 patent by offering to sell or selling in the United States, or importing into the United States, the suction models of the Saphyre products listed on Exhibit A.

6. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 17 and 54 (to the extent it depends from claim 1) of the '882 patent until the expiration of the '882 patent by offering to sell or selling in the United States, or importing into the United States, the Control RF products listed on Exhibit A.

IT IS FURTHER ORDERED that, with respect to United States Patent No. 6,224,592 ("the '592 patent"):

1. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 1, 3, 4, 11, 23, 26, 27, and 32 of the '592 patent until the expiration of the '592 patent by

inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A.

2. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 21 and 42 of the '592 patent until the expiration of the '592 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Control RF products listed on Exhibit A.

3. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 1, 3, 4, 11, 23, 26, 27, and 32 of the '592 patent until the expiration of the '592 patent by offering to sell or selling in the United States, or importing into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A.

4. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 21 and 42 of the '592

patent until the expiration of the '592 patent by offering to sell or selling in the United States, or importing into the United States, the Control RF products listed on Exhibit A.

IT IS FURTHER ORDERED that:

1. Defendant Smith & Nephew retrieve from all persons and entities, including sales representatives, distributors, executives, doctors, and hospitals, all Saphyre, ElectroBlade, and Control RF products listed in Exhibit A for which title has not passed from Smith & Nephew, Inc.
2. Defendant Smith & Nephew provide a copy of this order to each of its sales representatives, distribution executives, and other distributors for the Saphyre, ElectroBlade, and Control RF products listed in Exhibit A, whether or not such persons are employees of Smith & Nephew, Inc.
3. Defendant Smith & Nephew shall have a transition period from the date of this order until July 27, 2004³ to allow time for defendant Smith & Nephew to alert surgeons not to utilize the Saphyre, ElectroBlade, and Control RF probes listed on Exhibit A and for surgeons to receive instruction on alternative, non-infringing products.
4. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active

³The court granted Smith & Nephew a three month transition period commencing on April 27, 2004. (See D.I. 508) This transition period concludes on July 27, 2004.

concert or participation with any of them, are enjoined from committing any of the acts enumerated herein during this transition period.



United States District Judge

Exhibit A

The Infringing Products

I. Saphyre Products

Saphyre 90-degree, 3 mm Bipolar Ablation Probe, Integrated Cable,
REF 925001 / 7209686

Saphyre 90-degree, 3 mm Suction Bipolar Ablation Probe,
Integrated Cable, REF 925011 / 7209683

Saphyre 60-degree, 3 mm Bipolar Ablation Probe, Integrated Cable,
REF 925003 / 7209685

Saphyre 60-degree, 3 mm Suction Bipolar Ablation Probe,
Integrated Cable, REF 925013 / 7209682

Saphyre 90-degree HP Ablator, REF 7209684

Saphyre 90-degree HP Ablator with suction, REF 7209681

Pro-Saphyre 60-degree Small Joint with Suction, Oratec No. 925016

Pro-Saphyre 60-degree Small Joint, Oratec No. 925026

Saphyre II 90-degree HP with Suction, REF 7210112

Saphyre II 90-degree with Suction, REF 7210111

Saphyre II 60-degree with Suction, REF 7210113

Saphyre II 40-degree curved with Suction, REF 7210185

II. ElectroBlade Products

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Full Radius
Blade, REF 7205961

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Elite, REF
7209700

Dyonics Series 9000 ElectroBlade Resector 5.5 mm Full Radius
Vulcan Plug-in, REF 7205962

Dyonics Series 9000 ElectroBlade Resector 5.5 mm Elite Vulcan
Plug-in, REF 7209982

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Full Radius
Blade Vulcan Plug-in, REF 7209855

Dyonics Series 9000 ElectroBlade Resector 4.5 mm Elite Vulcan
Plug-in, REF 7209983

III. Control RF Products.

Dyonics Series 7000 RF Arthroscopic Probe, Type RS, REF 7205956

Dyonics Series 7000 RF Arthroscopic Probe, Type RSX, REF 7205957

Dyonics Series 7000 RF Arthroscopic Probe, Type RE, REF 7209034

Dyonics Series 7000 RF Arthroscopic Probe, Type REX, REF 7209035

Dyonics Series 7000 RF Arthroscopic Probe, Type AP, REF 7209036

Dyonics Series 7000 RF Arthroscopic Probe, Type APX, REF 7209037

Dyonics Series 7000 RF Arthroscopic Probe, Type MR, REF 7209038

Dyonics Series 7000 RF Arthroscopic Probe, Type MRX, REF 7209039

Dyonics Control RF Generator Adaptor, REF 7207908

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

O R D E R

At Wilmington this ~~4th~~ day of June, 2004, having conferred with counsel and having reviewed the papers submitted by the parties;¹

IT IS ORDERED that, with respect to the U.S. Patent No. 5,697,536 ("the '536 patent"):

1. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from:

(a) directly infringing claims 46, 47, and 56 of the '536 patent until the expiration of the '536 patent by making, using, offering to sell, or selling in the United States, or importing into the United States, the Saphyre,² ElectroBlade, or Control RF

¹Arthrocare's motion for entry of a permanent injunction (D.I. 485) is granted, and Smith & Nephew's motion to delay entry of injunction pending consideration of motion to stay injunction in Federal Circuit (D.I. 511) is denied as moot.

²When the court refers to the Saphyre products listed on Exhibit A herein, the court intends to include both the suction and non-suction models, unless otherwise specified.

products listed on Exhibit A attached hereto; (b) inducing the infringement of claims 46, 47, and 48 of the '536 patent until the expiration of the '536 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A ; and (c) contributing to the infringement of claims 46, 47, and 48 of the '536 patent until the expiration of the '536 patent by offering to sell or selling in the United States, or importing into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A.

IT IS FURTHER ORDERED that, with respect to United States Patent No. 5,697,882 ("the '882 patent"):

1. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 13 and 17 of the '882 patent until the expiration of the '882 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the non-suction models of the Saphyre products listed on Exhibit A.

2. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from

inducing the infringement of claim 54 of the '882 patent until the expiration of the '882 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the suction models of Saphyre products listed on Exhibit A.

3. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 17 and 54 of the '882 patent until the expiration of the '882 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Control RF products listed on Exhibit A.

4. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 13 and 17 of the '882 patent until the expiration of the '882 patent by offering to sell or selling in the United States, or importing into the United States, the non-suction models of the Saphyre products listed on Exhibit A.

5. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from

contributing to the infringement of claim 54 of the '882 patent until the expiration of the '882 patent by offering to sell or selling in the United States, or importing into the United States, the suction models of the Saphyre products listed on Exhibit A.

6. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 17 and 54 of the '882 patent until the expiration of the '882 patent by offering to sell or selling in the United States, or importing into the United States, the Control RF products listed on Exhibit A.

IT IS FURTHER ORDERED that, with respect to United States Patent No. 6,224,592 ("the '592 patent"):

1. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 1, 3, 4, 11, 23, 26, 27, and 32 of the '592 patent until the expiration of the '592 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A.

2. Defendant Smith & Nephew, its officers, agents,

servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from inducing the infringement of claims 21 and 42 of United States the '592 patent until the expiration of the '592 patent by inducing any person or entity to make, use, offer to sell, or sell in the United States, or import into the United States, the Control RF products listed on Exhibit A.

3. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 1, 3, 4, 11, 23, 26, 27, and 32 of the '592 patent until the expiration of the '592 patent by offering to sell or selling in the United States, or importing into the United States, the Saphyre, ElectroBlade, or Control RF products listed on Exhibit A.

4. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined from contributing to the infringement of claims 21 and 42 of the '592 patent until the expiration of the '592 patent by offering to sell or selling in the United States, or importing into the United States, the Control RF products listed on Exhibit A.

IT IS FURTHER ORDERED that:

1. Defendant Smith & Nephew retrieve from all persons and

entities, including sales representatives, distributors, executives, doctors, and hospitals, all Saphyre, ElectroBlade, and Control RF products listed in Exhibit A for which title has not passed from Smith & Nephew, Inc..

2. Defendant Smith & Nephew provide a copy of this order to each of its sales representatives, distribution executives, and other distributors for the Saphyre, ElectroBlade, and Control RF products listed in Exhibit A, whether or not such persons are employees of Smith & Nephew, Inc..

3. Defendant Smith & Nephew shall have a transition period from the date of this order until July 27, 2004³ to allow time for defendant Smith & Nephew to alert surgeons not to utilize the Saphyre, ElectroBlade, and Control RF probes listed on Exhibit A and for surgeons to receive instruction on alternative, non-infringing products.

4. Defendant Smith & Nephew, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of them, are enjoined committing any of the acts enumerated herein during this transition period.


United States District Judge

³The court granted Smith & Nephew a three month transition period commencing on April 27, 2004. (See D.I. 508) This transition period concludes on July 27, 2004.

Exhibit A

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Saphyre 60-degree, 3 mm Bipolar Ablation Probe, Integrated Cable,
REF 925003 / 7209685

Saphyre 60-degree, 3 mm Suction Bipolar Ablation Probe,
Integrated Cable, REF 925013 / 7209682

Saphyre 90-degree HP Ablator, REF 7209684

Saphyre 90-degree HP Ablator with suction, REF 7209681

Pro-Saphyre 60-degree Small Joint with Suction, Oratec No. 925016

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Blade, REF 7205961

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Dyonics Series 7000 RF Arthroscopic Probe, Type APX, REF 7209037

Dyonics Series 7000 RF Arthroscopic Probe, Type MR, REF 7209038

Dyonics Series 7000 RF Arthroscopic Probe, Type MRX, REF 7209039

Dyonics Control RF Generator Adaptor, REF 7207908

452

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

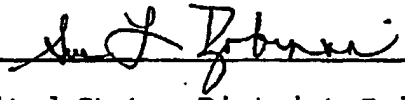
ARTHROCARE CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 01-504-SLR
)	
SMITH & NEPHEW, INC.,)	
)	
Defendant.)	

JUDGMENT IN A CIVIL CASE

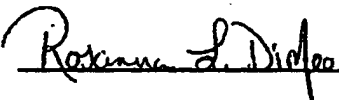
ArthroCare Corporation, plaintiff, and Smith & Nephew, defendant, came before the Court for a trial by jury. On May 12, 2003, the jury rendered a verdict (D.I. 405, copy attached) on the issues of patent infringement of claims 46, 47, and 56 of the '536 patent, claims 13, 17, and 54 of the '882 patent, claims 1, 3, 4, 11, 21, 23, 26, 27, 32, and 42 of the '592 patent and of patent invalidity of claims 46, 47, and 56 of the '536 patent, claims 13, 17, and 54 of the '882 patent, and claims 1, 3, 4, 11, 21, 23, 26, 27, 32, and 42 of the '592 patent and of patent enablement of claims 13, 17, and 54 of the '882 patent and of patent validity of the Certificate of Correction of claim 1 of the '882 patent. The jury found for plaintiff as to all issues.

Therefore,

IT IS ORDERED AND ADJUDGED that judgment be and is hereby entered in favor of ArthroCare Corporation, plaintiff, and against Smith & Nephew, defendant.


United States District Judge

Dated: June 20, 2003


(By) Deputy Clerk

405

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.

Defendant.

C.A. No. 01-504-SLR

SMITH & NEPHEW, INC.,

Counterclaim Plaintiff,

v.

ARTHROCARE CORPORATION, AND
ETHICON, INC.,

Counterclaim Defendants.

JURY VERDICT

We, the jury, unanimously find as follows:

L INFRINGEMENT OF ARTHROCARE'S PATENTS

A. The '536 Patent

Direct Infringement by Smith & Nephew of the '536 Patent

1. Do you find that Arthrocare has shown by a preponderance of the evidence that Smith & Nephew has directly infringed any of the following claims of the '536 patent with its Saphyre, ElectroBlade, or Control RF products? ("YES" answers to these questions are findings for ArthroCare. "NO" answers are findings for Smith & Nephew.)

Patent	Claim	Saphyre	ElectroBlade	Control RF
'536	46	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'536	47	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'536	56	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO

Inducement of Infringement by Smith & Nephew

2. Do you find that Arthrocare has shown by a preponderance of the evidence that Smith & Nephew has induced infringement by others of any of the following claims of the '536 patent with its Saphyre, ElectroBlade, or Control RF products? ("YES" answers to these questions are findings for ArthroCare. "NO" answers are findings for Smith & Nephew.)

Patent	Claim	Saphyre	ElectroBlade	Control RF
'536	46	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'536	47	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'536	56	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO

Contributory Infringement by Smith & Nephew

3. Do you find that Arthrocare has shown by a preponderance of the evidence that Smith & Nephew has contributed to the infringement any of the following claims of the '536 patent with its Saphyre, ElectroBlade, or Control RF products? ("YES" answers to these questions are findings for ArthroCare. "NO" answers are findings for Smith & Nephew.)

Patent	Claim	Saphyre	ElectroBlade	Control RF
'536	46	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'536	47	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'536	56	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO

B. The '882 Patent

Validity of ArthroCare's Certificate of Correction for the '882 Patent

4. Do you find that Smith & Nephew has shown by clear and convincing evidence that the certificate of correction for claim 1 of the '882 patent is invalid? (A "YES" answer to this question is a finding for Smith & Nephew. A "NO" answer is a finding for ArthroCare.)

Patent	Claim	Invalid
'882	1	YES <input checked="" type="radio"/> NO

Answer questions 5-6 only if you have answered "NO" in question 4.

Inducement of Infringement by Smith & Nephew of the '882 Patent

5. Do you find that Arthrocare has shown by a preponderance of the evidence that Smith & Nephew has induced infringement by others of any of the following claims of the '882 patent with its Saphyre or Control RF products? ("YES" answers to these questions are findings for ArthroCare. "NO" answers are findings for Smith & Nephew.)

Patent	Claim	Saphyre	Smith & Nephew with Saphyre	Control RF	Control RF
'882	13	<input checked="" type="radio"/> YES NO			
'882	17	<input checked="" type="radio"/> YES NO			<input checked="" type="radio"/> YES NO
'882	54		<input checked="" type="radio"/> YES NO		<input checked="" type="radio"/> YES NO

Contributory Infringement by Smith & Nephew of the '882 Patent

6. Do you find that Arthrocare has shown by a preponderance of the evidence that Smith & Nephew has contributed to the infringement of any of the following claims of the '882 patent with its Saphyre or Control RF products? ("YES" answers to these questions are findings for ArthroCare. "NO" answers are findings for Smith & Nephew.)

Patent	Claim	Saphyre	Saphyre with suction	Electroblade	Control RF
'882	13	<input checked="" type="radio"/> YES <input type="radio"/> NO			
'882	17	<input checked="" type="radio"/> YES <input type="radio"/> NO			<input checked="" type="radio"/> YES <input type="radio"/> NO
'882	54		<input checked="" type="radio"/> YES <input type="radio"/> NO		<input checked="" type="radio"/> YES <input type="radio"/> NO

C. The '592 Patent

Inducement of Infringement by Smith & Nephew of the '592 Patent

7. Do you find that Arthrocare has shown by a preponderance of the evidence that Smith & Nephew has induced infringement by others of any of the following claims of the '592 patent with its Saphyre, ElectroBlade, or Control RF products? ("YES" answers to these questions are findings for ArthroCare. "NO" answers are findings for Smith & Nephew.)

Patent	Claim	Saphyre	Electroblade	Control RF
'592	1	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	3	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	4	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	11	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	21			<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	23	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	26	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	27	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	32	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	42			<input checked="" type="radio"/> YES <input type="radio"/> NO

Contributory Infringement by Smith & Nephew of the '592 Patent

8. Do you find that Arthrocare has shown by a preponderance of the evidence that Smith & Nephew has contributed to the infringement of any of the following claims of the '592 patent with its Saphyre, ElectroBlade, or Control RF products? ("YES" answers to these questions are findings for ArthroCare. "NO" answers are findings for Smith & Nephew.)

Patent	Claim	Saphyre	Electroblade	Control RF
'592	1	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	3	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	4	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	11	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	21			<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	23	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	26	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	27	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	32	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO	<input checked="" type="radio"/> YES <input type="radio"/> NO
'592	42			<input checked="" type="radio"/> YES <input type="radio"/> NO

II. VALIDITY OF ARTHROCARE'S PATENTS

A. Anticipation of ArthroCare's Patents

9. Do you find that Smith & Nephew has shown by clear and convincing evidence that the following claims of the patents-in-suit are invalid due to anticipation? (A "YES" answer to this question is a finding for Smith & Nephew. A "NO" answer is a finding for ArthroCare.)

The '536 Patent

	Anticipated	
Claim 46	YES	<input checked="" type="radio"/> NO
Claim 47	YES	<input checked="" type="radio"/> NO
Claim 56	YES	<input checked="" type="radio"/> NO

The '882 Patent

	Anticipated	
Claim 13	YES	<input checked="" type="radio"/> NO
Claim 17	YES	<input checked="" type="radio"/> NO
Claim 54	YES	<input checked="" type="radio"/> NO

The '592 Patent

	Anticipated	
Claim 1	YES	<input checked="" type="radio"/> NO
Claim 3	YES	<input checked="" type="radio"/> NO
Claim 4	YES	<input checked="" type="radio"/> NO
Claim 11	YES	<input checked="" type="radio"/> NO
Claim 21	YES	<input checked="" type="radio"/> NO
Claim 23	YES	<input checked="" type="radio"/> NO
Claim 26	YES	<input checked="" type="radio"/> NO
Claim 27	YES	<input checked="" type="radio"/> NO
Claim 32	YES	<input checked="" type="radio"/> NO
Claim 42	YES	<input checked="" type="radio"/> NO

D. Enablement of ArthroCare's Patent

10. Do you find that Smith & Nephew has shown by clear and convincing evidence that the following claims are invalid for lack of enablement? (A "YES" answer to this question is a finding for Smith & Nephew. A "NO" answer is a finding for ArthroCare.)

Patent	Claims	Invalid
'882	13, 17, 54	YES <input checked="" type="radio"/> NO

Each Juror should sign the verdict form to reflect that a unanimous verdict has been reached.

Dated: May 2, 2003

Dolphine Adkins
Foreperson

Stacy Miranda

Christine M. Murray

Sharon Hansen

ALL HOURS
ED. 10/10/03

Bernard H. Price

Jeff L. Byers

Carol Hansen

John X. Zahner

A 353

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION.,)
)
Plaintiff,)
)
v.) Civil Action No. 01-504-SLR
)
SMITH & NEPHEW, INC.,)
)
Defendant.)

MEMORANDUM ORDER

At Wilmington this 9th day of April, 2003, having heard oral argument and having reviewed papers submitted in connection therewith;

IT IS ORDERED that the disputed claim language in United States Patent Nos. 5,697,536; 5,697,882; and 6,224,592, as identified by the above referenced parties, shall be construed as follows, consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit:¹

¹The court notes that claim construction is not final until judgment is entered. The parties apparently developed their claim construction with a focus on obtaining summary judgment of infringement or invalidity. If, on a more developed record, the court finds the current claim construction to be in error, the claims will be re-construed accordingly.

04/07

1. "Connector."

The court shall apply the ordinary definition of the word "connector." The word connect means "to bind or fasten together; join or unite; link[.]"² The word "connector," in terms of the '536 patent, shall be construed to mean "a structure that electrically links the electrode terminal to the high frequency power supply."

2. "Electrically Conducting Fluid Supply."

Consistent with the prosecution history, the phrase "electrically conducting fluid supply" shall be construed to mean "a medical container that stores electrically conducting fluid." (D.I. 267, Ex. 10 at 4-5) An example of a medical container is an IV bag. An example of electrically conducting fluid is isotonic saline. (Id.)

4. "Spacing a Return Electrode Away From the Body Structure" and "the Return Electrode is Not in Contact with the Body Structure."

The claim limitation "the return electrode is not in contact with the body structure" is clear - the return electrode is not to contact the body at all during the performance of the claimed method.

²The Random House College Dictionary, 285 (revised ed. 1980).

5. "Electrically Conducting Fluid" and "Electrically Conductive Fluid."

Consistent with the ordinary definition, "electrically conducting fluid" and "electrically conductive fluid" shall be construed to mean "any fluid that facilitates the passage of electrical current." Examples of electrically conducting fluids are blood and saline.

6. "Directing or Delivering the Electrically Conductive Fluid to the Target Site."

This phrase shall be construed consistent with its ordinary meaning; no further construction is necessary.

7. "Electrode Terminal."

Consistent with the intrinsic evidence of the patents in suit, "electrode terminal" means "one or more active electrodes."

8. "Active Electrode."

The court shall apply the ordinary definition of the term "active electrode" in the relevant art. The term "active electrode" means "a stimulating electrode . . . applied to tissue for stimulation and distinguished from [a return electrode] by having a smaller area of contact, thus affording a higher current density."³

³The New IEEE Standard Dictionary of Electrical and Electronics Terms, 13 (5th ed. 1993).

9. "Return Electrode."

As contrasted with an active electrode, the term "return electrode" means "an electrode having a larger area of contact than an active electrode, thus affording a lower current density."⁴

10. "Insulating Member."

The court shall apply the ordinary definition of the phrase "insulating member." Thus, the phrase "insulating member" shall be construed to mean "a member which provides a high degree of resistance to the passage of charge."

11. "500 to 1400 Volts Peak to Peak."

This phrase shall be construed consistent with its ordinary meaning; no further construction is necessary.

12. "Through the Region of the Target Site."

This phrase shall be construed consistent with its ordinary meaning; no further construction is necessary.

13. "Immersing."

The court shall apply the ordinary definition of the term "immersing." The term "immersing" shall be construed to mean "to plunge into or place under a fluid[.]"⁵

⁴The court notes that the area of contact in the present invention contacts the electrically conductive fluid. In the prior art, the area of contact contacted the body.

⁵The Random House College Dictionary, 664 (revised ed. 1980).

14. "Electrosurgical System."

The court shall apply the ordinary definition of the term "system." The term "system" shall be construed to mean "an assemblage or combination of things or parts forming a unitary whole[.]"⁶

15. "Distal End" and "Proximal End."

The court shall apply the ordinary definition of the terms "distal" and "proximal." The term "distal end" shall be construed to mean "the end situated away from the point of origin or attachment."⁷ The term "proximal end" shall be construed to mean "the end situated toward the point of origin or attachment."⁸


United States District Judge

⁶The Random House College Dictionary, 1335 (revised ed. 1980).

⁷See The Random House College Dictionary, 385 (revised ed. 1980).

⁸See The Random House College Dictionary, 1066 (revised ed. 1980).



US005697536A

United States Patent [19]

Eggers et al.

[11] Patent Number: 5,697,536

[45] Date of Patent: Dec. 16, 1997

[54] **SYSTEM AND METHOD FOR
ELECTROSURGICAL CUTTING AND
ABLATION**[75] Inventors: Philip E. Eggers, Dublin, Ohio; Hira
V. Thapliyal, Los Altos, Calif.[73] Assignee: Arthrocare Corporation, Sunnyvale,
Calif.

[21] Appl. No.: 746,800

[22] Filed: Nov. 18, 1996

Related U.S. Application Data[60] Division of Ser. No. 485,219, Jan. 7, 1995, which is a
continuation-in-part of Ser. No. 446,767, Jan. 2, 1995,
which is a continuation-in-part of Ser. No. 59,681, May 10,
1993, abandoned, which is a continuation-in-part of Ser. No.
958,977, Oct. 9, 1992, Pat. No. 5,366,443, which is a
continuation-in-part of Ser. No. 817,575, Jan. 7, 1992,
abandoned.[51] Int. Cl.⁶ A61M 37/00

[52] U.S. Cl. 604/114; 604/22

[58] Field of Search 604/22, 43, 48,
604/113, 114, 264, 271, 280; 606/31, 28,
29, 39, 41, 45[56] **References Cited****U.S. PATENT DOCUMENTS**

2,050,904	8/1936	Trice .	
4,202,337	5/1980	Hren et al.	128/303
4,228,800	10/1980	Degler, Jr. et al.	128/303
4,326,529	4/1982	Doss	128/303.1
4,381,007	4/1983	Doss	128/303.1
4,476,862	10/1984	Pao	128/303.17
4,532,924	8/1985	Auth et al.	128/303.17
4,567,890	2/1986	Ohta et al.	128/303.13
4,593,691	6/1986	Lindstrom et al.	128/303
4,658,817	4/1987	Hardy	128/303
4,674,499	6/1987	Pao	128/303
4,709,698	12/1987	Johnston et al.	128/303
4,765,331	8/1988	Petruzzi et al.	128/303
4,931,047	6/1990	Broadwin et al.	604/22
4,936,301	6/1990	Retroth et al.	606/45
4,943,290	7/1990	Retroth et al.	606/45

4,955,377	9/1990	Lennox et al.	128/401
4,967,765	11/1990	Turner et al.	128/785
4,976,711	12/1990	Parins et al.	606/48
4,979,948	12/1990	Geddes et al.	606/33
4,998,933	3/1991	Eggers et al.	606/41

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

515 867	12/1992	European Pat. Off.	A61B 17/36
0 740 926	11/1996	European Pat. Off.	A61B 17/39
WO 90/07303	7/1990	WIPO	A61B 17/39
WO 92/21278	12/1992	WIPO	A61B 5/04
WO 93/13816	7/1993	WIPO	A61B 17/36
WO 94/14383	7/1994	WIPO	A61B 17/36

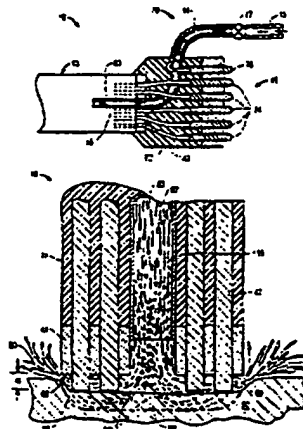
OTHER PUBLICATIONSP.C. Nardella (1989) *SPIE* 1068:42-49 Radio Frequency
Energy and Impedance Feedback.Rand et al. (1985) *J. Arthro. Surg.* 1:242-246 Effect of
Electrocautery on Fresh Human Articular Cartilage.

Primary Examiner—Manuel Mendez

Attorney, Agent, or Firm—Townsend and Townsend and
Crew LLP[57] **ABSTRACT**

An electrosurgical probe (10) comprises a shaft (13) having an electrode array (12) at its distal end and a connector (19) at its proximal end for coupling the electrode array to a high frequency power supply (28). The shaft includes a return electrode (55, 56) recessed from its distal end and enclosed within an insulating jacket (18). The return electrode defines an inner passage (83) electrically connected to both the return electrode and the electrode array for passage of an electrically conducting liquid (50). By applying high frequency voltage to the electrode array and the return electrode, the electrically conducting liquid generates a current flow path between the target site and the return electrode so that target tissue may be cut or ablated. The probe is particularly useful in dry environments, such as the mouth or abdominal cavity, because the electrically conducting liquid provides the necessary return current path between the return electrode and the target site.

64 Claims, 10 Drawing Sheets



U.S. PATENT DOCUMENTS

5,009,656	4/1991	Reimels	606/48	5,312,400	5/1994	Bales et al.	
5,057,105	10/1991	Malone et al.	606/28	5,314,406	5/1994	Arias et al.	
5,083,565	1/1992	Parins	128/642	5,324,254	6/1994	Phillips	
5,102,410	4/1992	Dressel	606/15	5,334,140	8/1994	Phillips	
5,108,391	4/1992	Flachenecker et al.	606/38	5,334,183	8/1994	Wuchinich	
5,178,620	1/1993	Eggers et al.	606/41	5,336,217	8/1994	Buyts et al.	606/9
5,195,959	3/1993	Smith	604/34	5,336,220	8/1994	Ryan et al.	
5,197,963	3/1993	Parins		5,342,357	8/1994	Nardella	
5,217,455	6/1993	Tan	606/9	5,366,443	11/1994	Eggers et al.	606/114
5,261,410	11/1993	Alfano et al.	128/664	5,370,642	12/1994	Keller	606/9
5,267,994	12/1993	Gentelia et al.		5,380,277	1/1995	Phillips	
5,273,524	12/1993	Fox et al.		5,380,316	1/1995	Aita et al.	606/7
5,277,201	1/1994	Stern	607/98	5,383,876	1/1995	Nardella	
5,281,216	1/1994	Kliok	606/42	5,383,917	1/1995	Desai et al.	607/702
5,282,797	2/1994	Chess	606/9	5,389,096	2/1995	Aita et al.	606/15
5,290,273	3/1994	Tan	606/9	5,395,312	3/1995	Desai	
5,290,282	3/1994	Casscells	606/29	5,419,767	5/1995	Eggers et al.	604/114
5,300,069	4/1994	Hunsberger et al.		5,423,803	6/1995	Tankovich	606/9
5,304,170	4/1994	Green	606/9	5,445,634	8/1995	Keller	606/9
5,312,395	5/1994	Tan et al.	606/9	5,454,809	10/1995	Jaanssen	606/41
				5,569,242	10/1996	Lax et al.	606/42

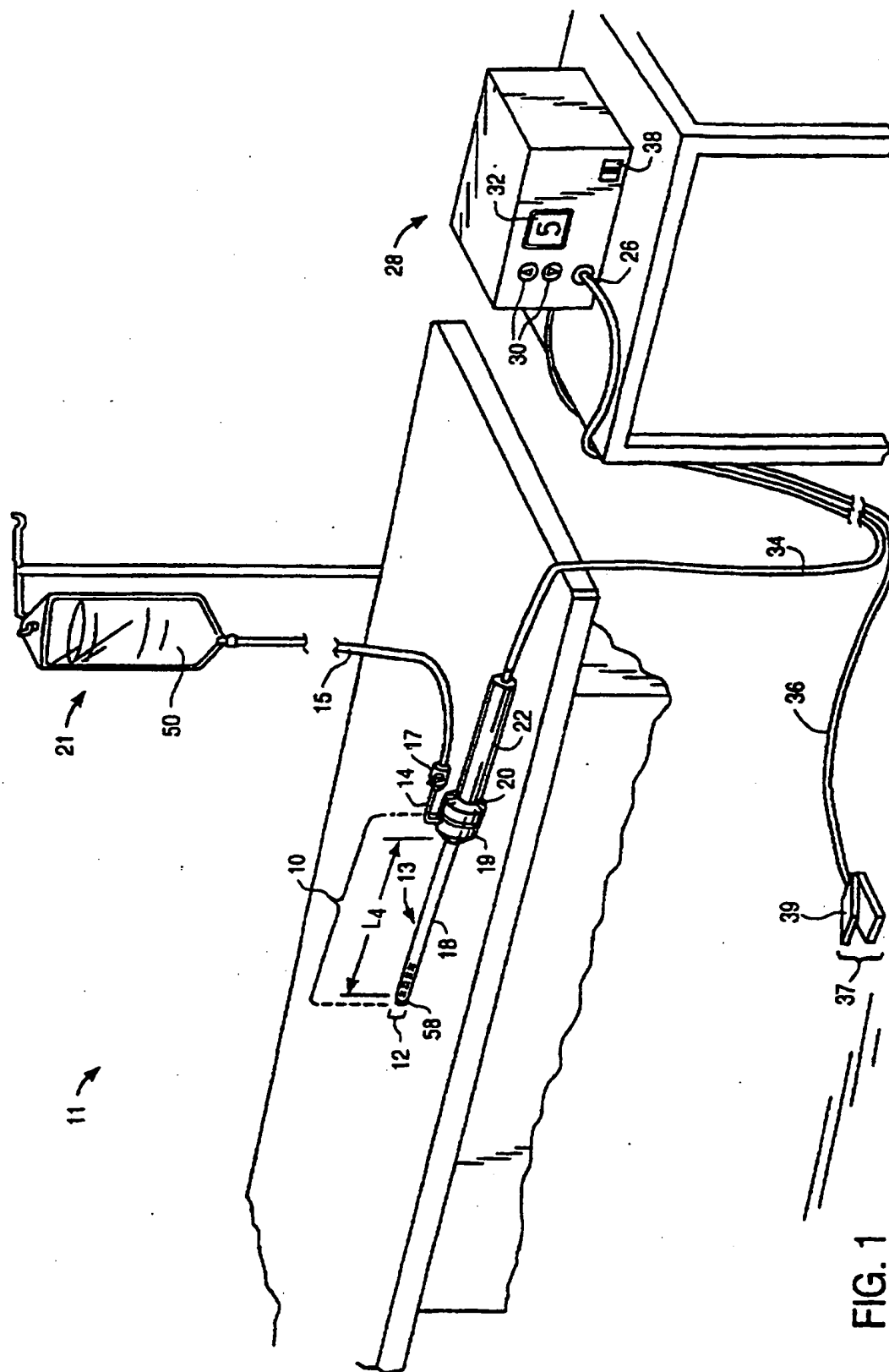


FIG. 1

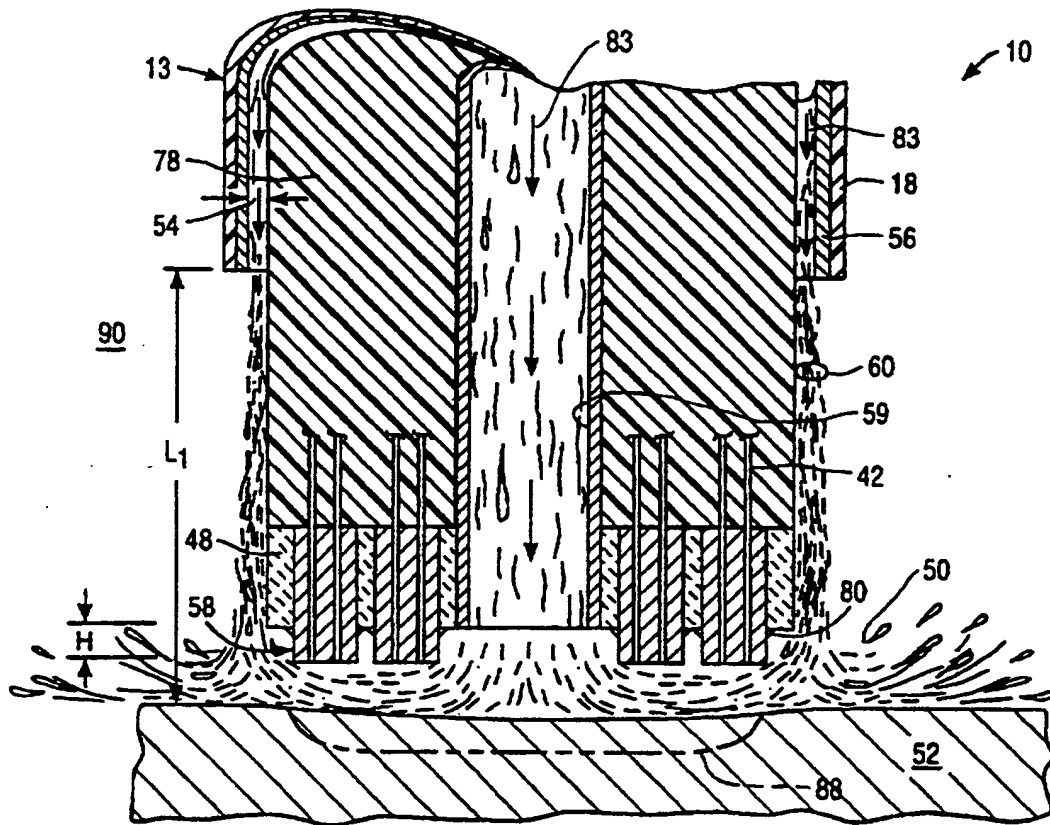


FIG. 2A

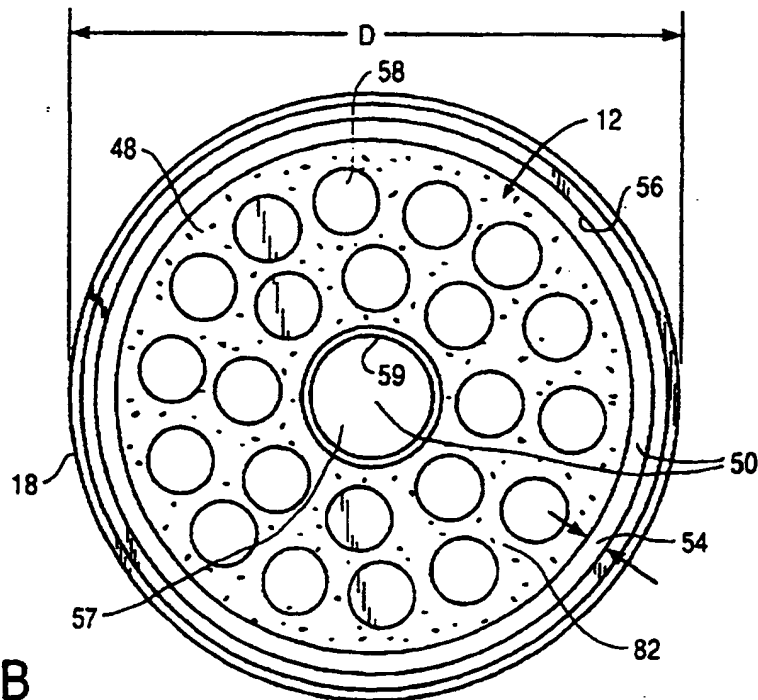


FIG. 2B

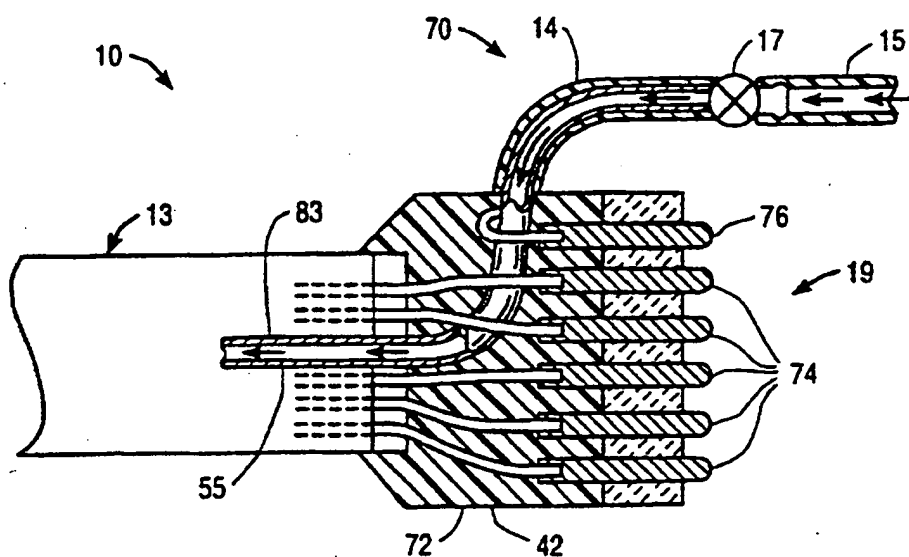


FIG. 2C

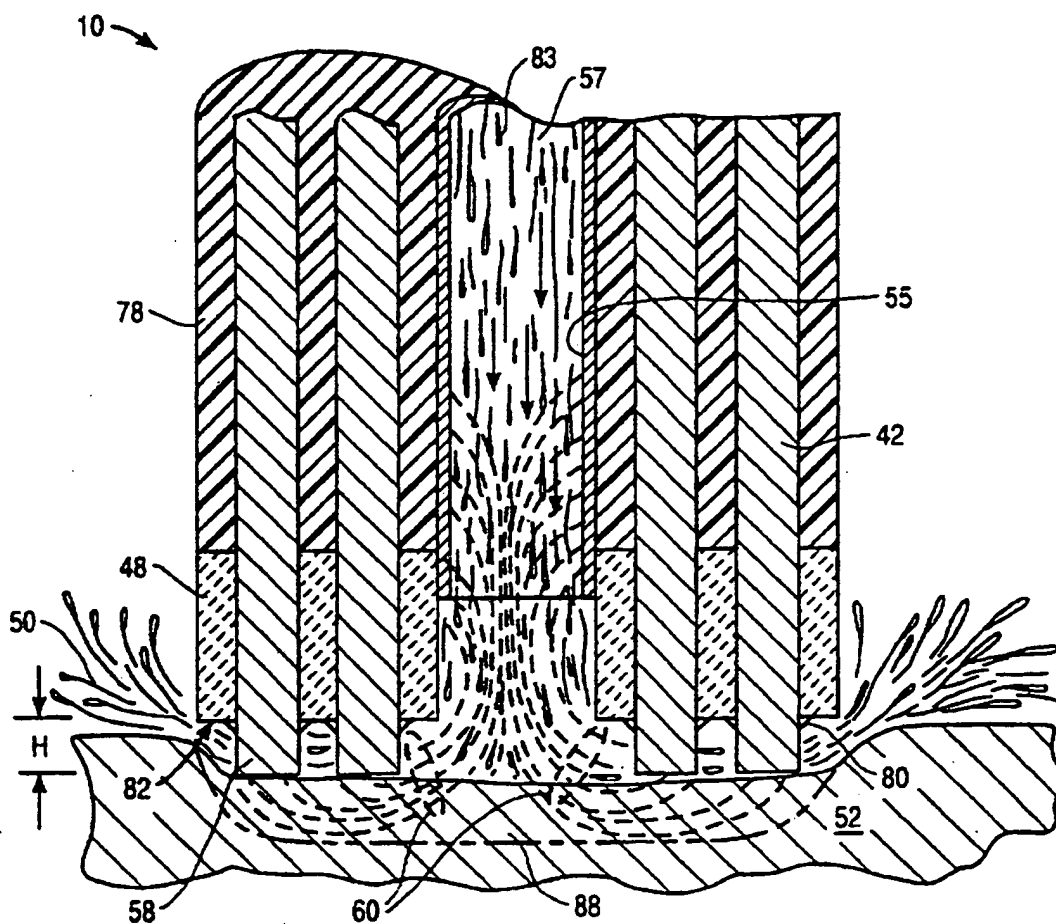


FIG. 3

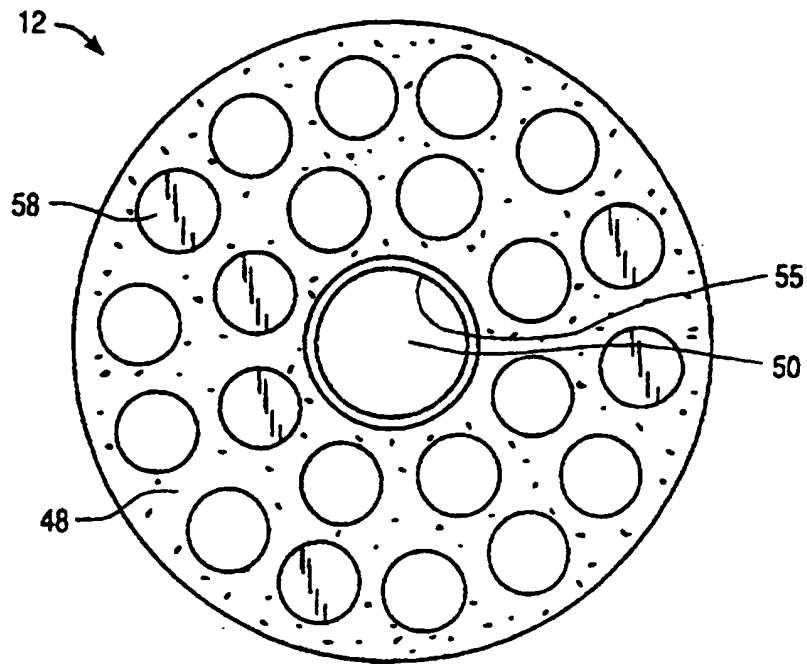


FIG. 4

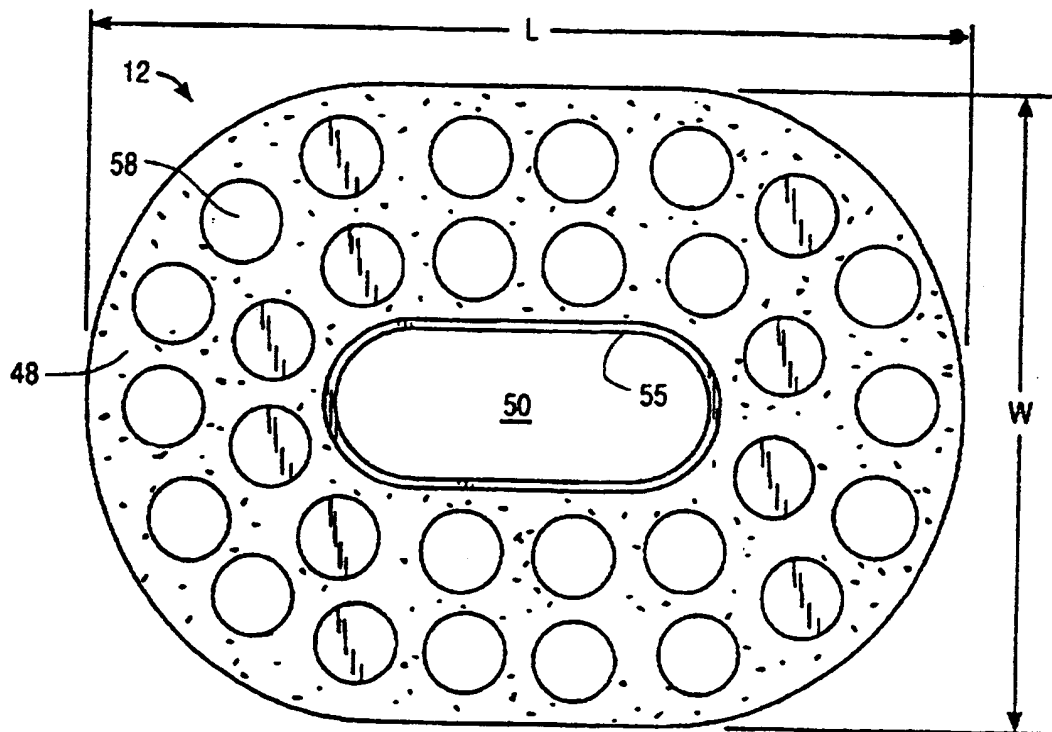


FIG. 5

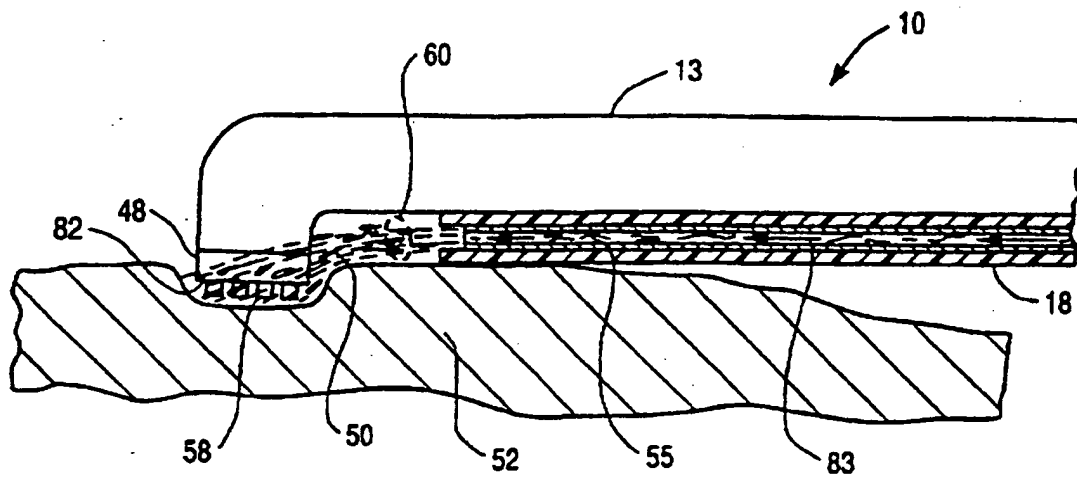


FIG. 6

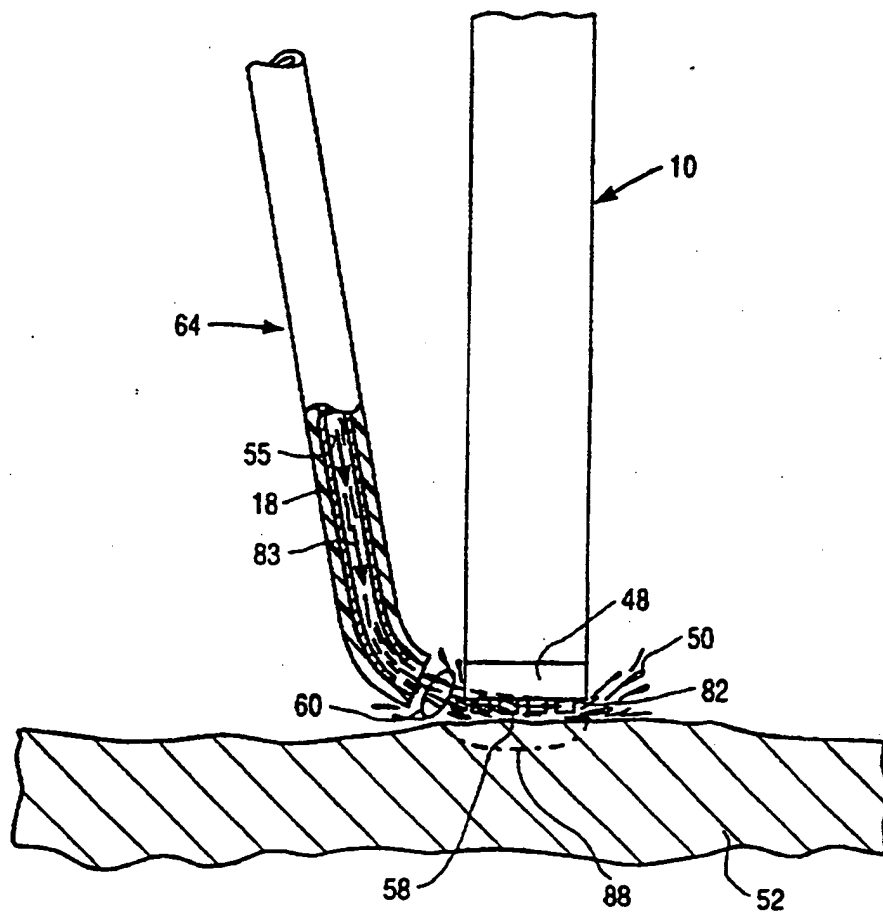


FIG. 7

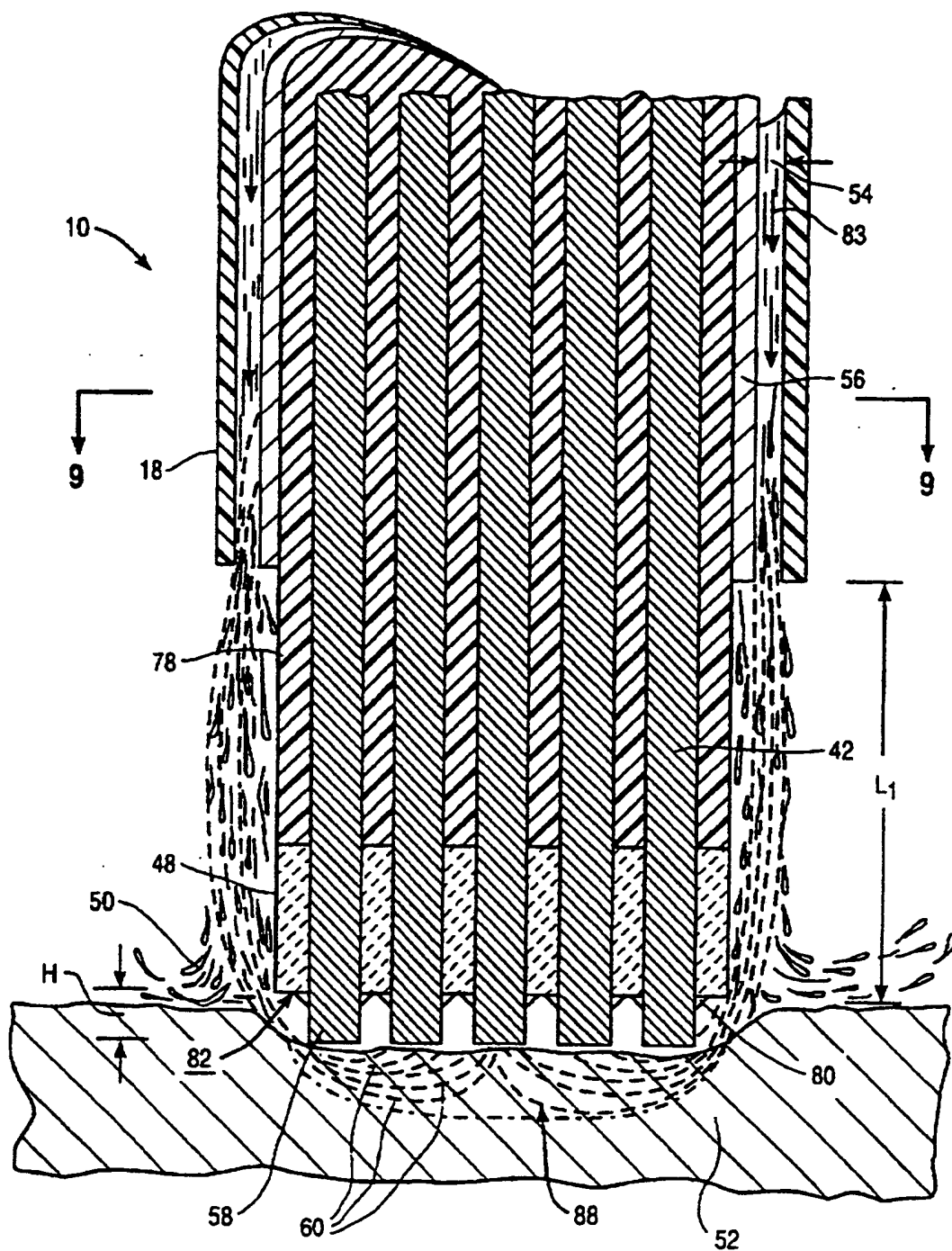


FIG. 8

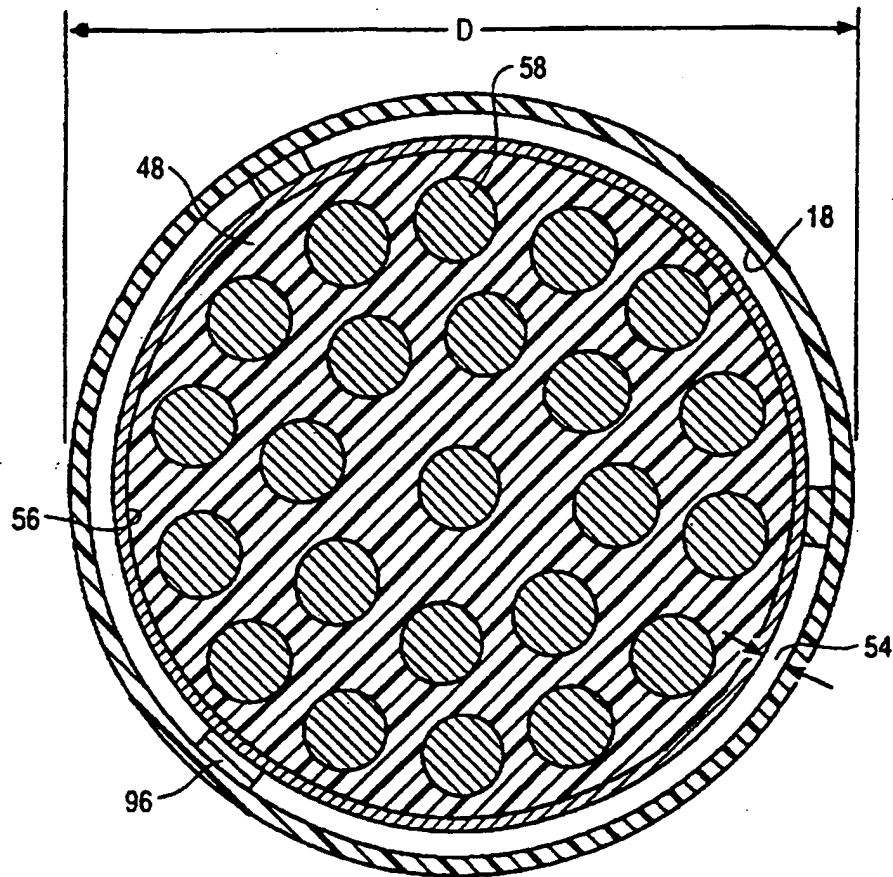


FIG. 9

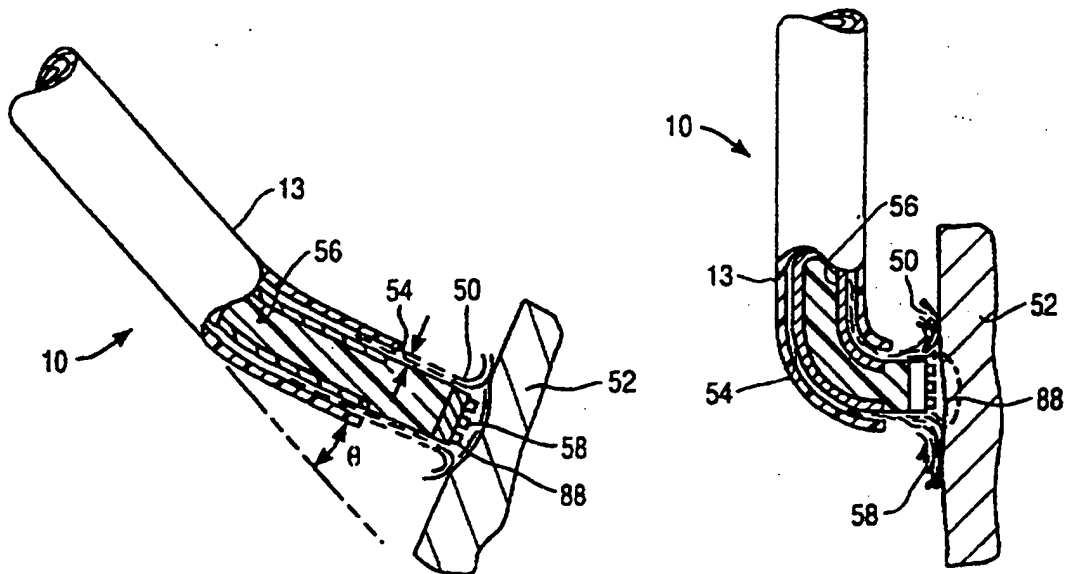


FIG. 10

FIG. 11

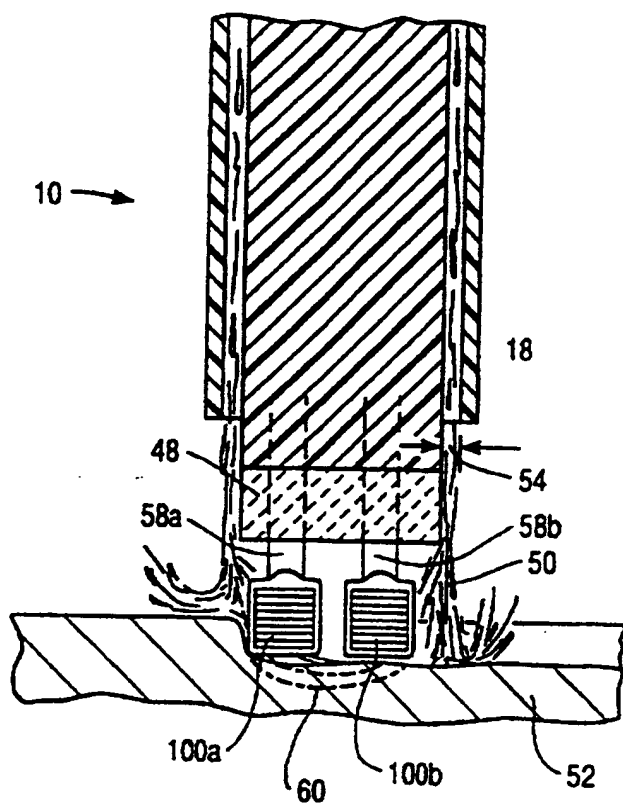


FIG. 12

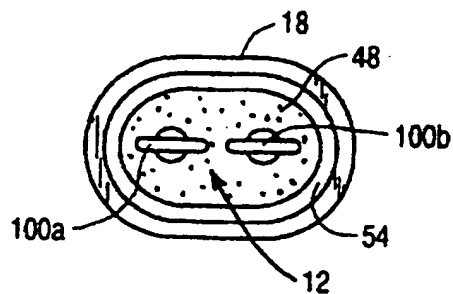


FIG. 13

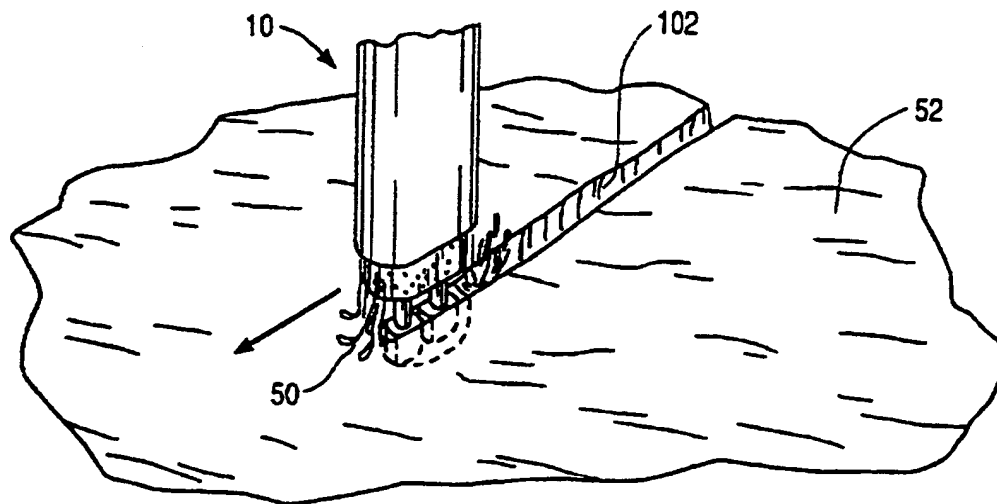


FIG. 14

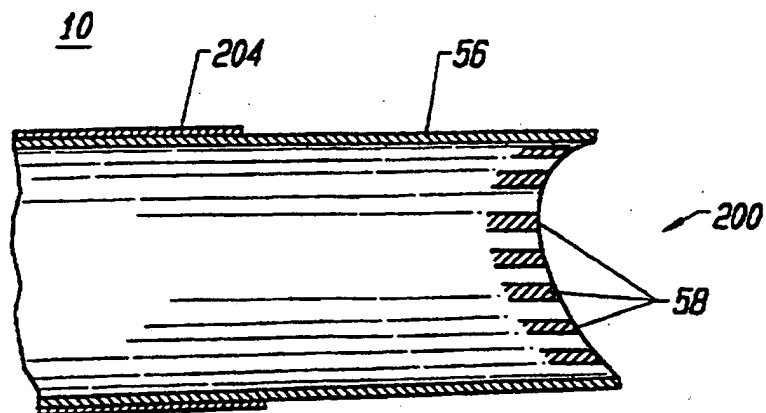


FIG. 15

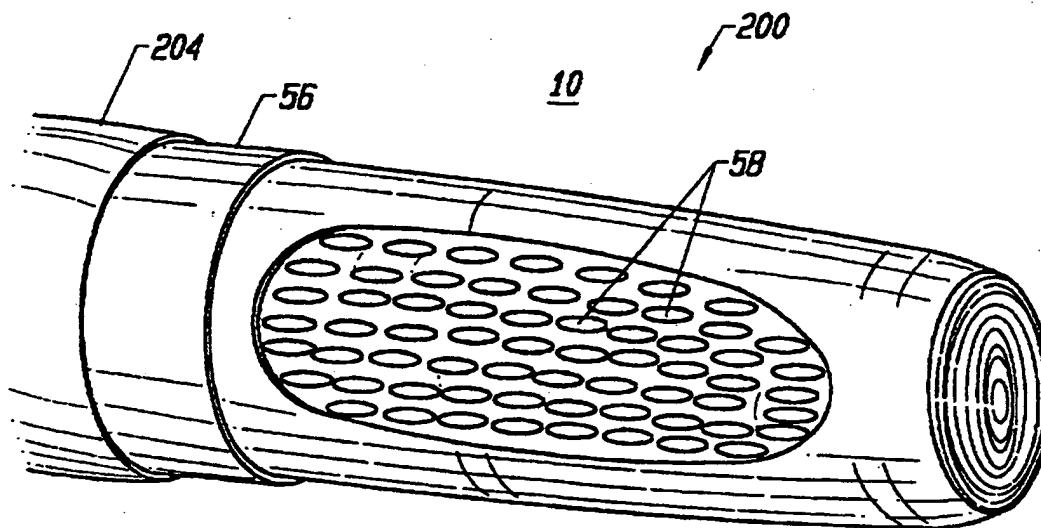
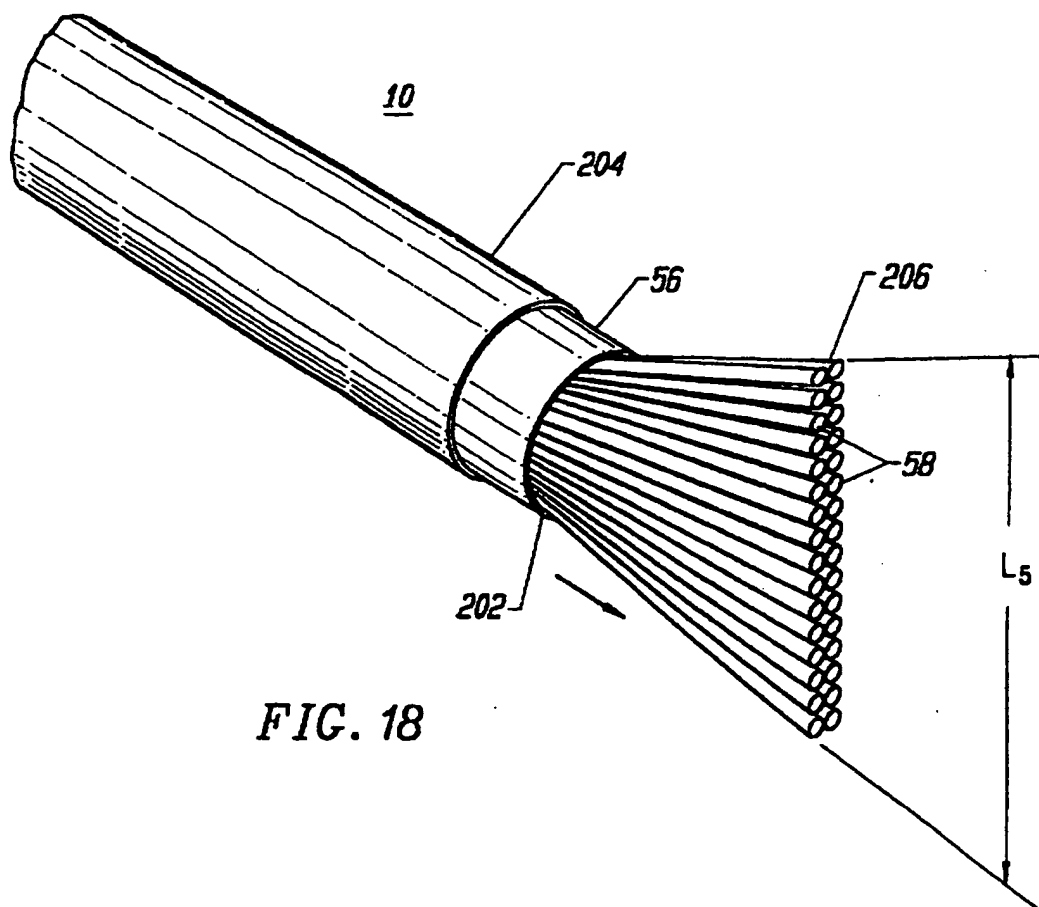
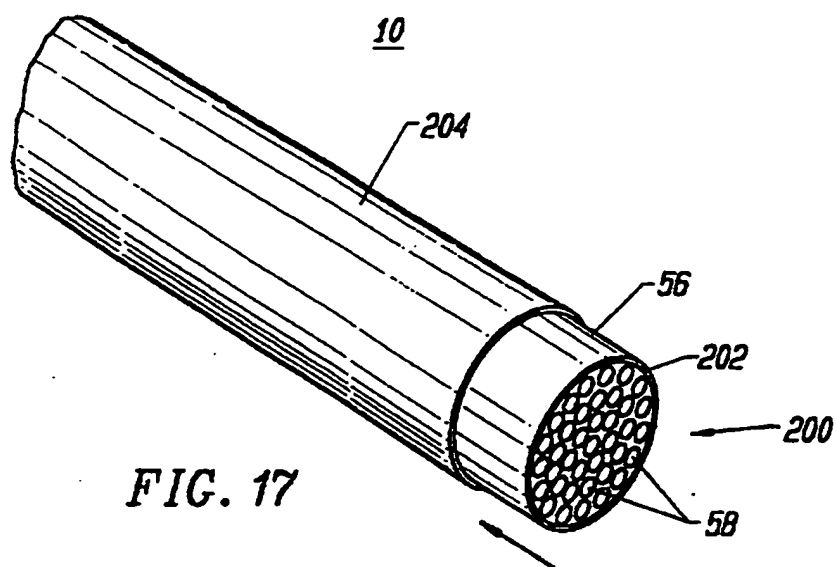


FIG. 16



SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION

BACKGROUND OF THE INVENTION

This is a Division of application Ser. No. 08/485,219 filed Jun. 7, 1995 pending, which is a continuation-in-part of application Ser. No. 08/446,767 filed on Jun. 2, 1995 and pending; which was a continuation-in-part of application Ser. No. 08/059,681, filed on May 10, 1993, now abandoned; which was a continuation-in-part of application Ser. No. 07/958,977, filed on Oct. 9, 1992, now U.S. Pat. No. 5,366,443; which was a continuation-in-part of application Ser. No. 07/817,575, filed on Jan. 7, 1992, now abandoned; the full disclosures of which are incorporated herein by reference.

1. Field of the Invention

The present invention relates generally to the field of electrosurgery and, more particularly, to surgical devices and methods which employ high frequency voltage to cut and ablate tissue.

The field of electrosurgery includes a number of loosely related surgical techniques which have in common the application of electrical energy to modify the structure or integrity of patient tissue. Electrosurgical procedures usually operate through the application of very high frequency currents to cut or ablate tissue structures, where the operation can be monopolar or bipolar. Monopolar techniques rely on external grounding of the patient, where the surgical device defines only a single electrode pole. Bipolar devices comprise both electrodes for the application of current between their surfaces.

Electrosurgical procedures and techniques are particularly advantageous since they generally reduce patient bleeding and trauma associated with cutting operations. Additionally, electrosurgical ablation procedures, where tissue surfaces and volume may be reshaped, cannot be duplicated through other treatment modalities.

Current electrosurgical devices and procedures, however, suffer from a number of disadvantages. For example, monopolar devices generally direct electric current along a defined path from the exposed or active electrode through the patient's body to the return electrode, which is externally attached to a suitable location on the patient. This creates the potential danger that the electric current will flow through undefined paths in the patient's body, thereby increasing the risk of unwanted electrical stimulation to portions of the patient's body. In addition, since the defined path through the patient's body has a relatively high impedance (because of the large distance or resistivity of the patient's body), large voltage differences must typically be applied between the return and active electrodes in order to generate a current suitable for ablation or cutting of the target tissue. This current, however, may inadvertently flow along body paths having less impedance than the defined electrical path, which will substantially increase the current flowing through these paths, possibly causing damage to or destroying surrounding tissue.

Bipolar electrosurgical devices have an inherent advantage over monopolar devices because the return current path does not flow through the patient. In bipolar electrosurgical devices, both the active and return electrode are typically exposed so that they may both contact tissue, thereby providing a return current path from the active to the return electrode through the tissue. One drawback with this configuration, however, is that the return electrode may

cause tissue desiccation or destruction at its contact point with the patient's tissue. In addition, the active and return electrodes are typically positioned close together to ensure that the return current flows directly from the active to the return electrode. The close proximity of these electrodes generates the danger that the current will short across the electrodes, possibly impairing the electrical control system and/or damaging or destroying surrounding tissue.

The use of electrosurgical procedures (both monopolar and bipolar) in electrically conductive environments can be further problematic. For example, many arthroscopic procedures require flushing of the region to be treated with isotonic saline (also referred to as normal saline), both to maintain an isotonic environment and to keep the field of viewing clear. The presence of saline, which is a highly conductive electrolyte, can also cause shorting of the electrosurgical electrode in both monopolar and bipolar modes. Such shorting causes unnecessary heating in the treatment environment and can further cause non-specific tissue destruction.

In response to the various problems associated with electrosurgical procedures in electrically conductive environments, new methods and devices have been developed by the applicant. These methods and devices provide selective power delivery to the target tissue while minimizing power delivery to the surrounding electrically conductive irrigant. These methods are particularly useful in isotonic saline filled body cavities, such as arthroscopic, urologic or gynecologic cavities. The irrigant flooded body cavity provides good visibility, facilitates the removal of bubbles or other debris, minimizes the possibility of air embolism and protects certain tissue from dehydration. Such methods and devices are more fully described in previously filed, commonly assigned applications Ser. Nos. 08/059,681, 07/958,977 and 07/817,575, the full disclosures of which have been incorporated by reference.

Many surgical procedures, such as oral, laparoscopic and open surgical procedures, are not performed with the target tissue submerged under an irrigant. In laparoscopic procedures, such as the resection of the gall bladder from the liver, for example, the abdominal cavity is pressurized with carbon dioxide (pneumoperitoneum) to provide working space for the instruments and to improve the surgeon's visibility of the surgical site. Other procedures, such as the ablation of muscle or gingiva tissue in the mouth or the ablation and necrosis of diseased tissue, are also typically performed in a "dry" environment or field (i.e., not submerged under an electrically conducting irrigant).

For these and other reasons, improved systems and methods are desired for the electrosurgical ablation and cutting of tissue. These systems and methods should be capable of providing a direct return current path from the active electrode, through the target site, to the return electrode to minimize the dangers of electrical current flowing through undefined paths in the patient's body. The system should also be configured to minimize contact between the return electrode and surrounding tissue and to avoid current shorting between the active and return electrodes. Preferably, the system will be configured to apply high frequency voltage for the cutting and ablation of tissue in relatively dry environments, such as those encountered in oral, laparoscopic and open surgical procedures.

2. Description of the Background Art

Devices incorporating radio frequency electrodes for use in electrosurgical and electrocautery techniques are described in Rand et al. (1985) *J. Arthro. Surg.* 1: 242-246

and U.S. Pat. Nos. 5,281,216; 4,943,290; 4,936,301; 4,593,691; 4,228,800; and 4,202,337. U.S. Pat. Nos. 4,943,290 and 4,036,301 describe methods for injecting non-conducting liquid over the tip of a monopolar electrosurgical electrode to electrically isolate the electrode, while energized, from a surrounding electrically conducting irrigant. U.S. Pat. Nos. 5,195,959 and 4,674,499 describe monopolar and bipolar electrosurgical devices, respectively, that include a conduit for irrigating the surgical site.

SUMMARY OF THE INVENTION

The present invention provides an apparatus and method for selectively applying electrical energy to structures within a patient's body. The apparatus and method allow the surgical team to perform electrosurgical interventions, such as ablation and cutting of body structures, without requiring the tissue to be submerged in an electrically conducting irrigant, such as isotonic saline. The apparatus and method of the present invention are particularly useful for treating and shaping gingiva, for tissue dissection, e.g. separation of gall bladder from the liver, and ablation and necrosis of diseased tissue, such as tumors.

The method of the present invention comprises positioning an electrosurgical probe adjacent the target tissue so that at least one active electrode is brought into at least partial contact or close proximity with the target site. Electrically conducting liquid, such as isotonic saline, is directed through a fluid path past a return electrode and to the target site to generate a current flow path between the target site and the return electrode. High frequency voltage is then applied between the active and return electrode through the current flow path created by the electrically conducting liquid in either a bipolar or monopolar manner. The probe may then be translated, reciprocated or otherwise manipulated to cut the tissue or effect the desired depth of ablation.

The above described method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid), such as open, laparoscopic or oral surgery, because the electrically conducting liquid provides a suitable current flow path from the target site to the return electrode. The active electrode is preferably disposed at the distal end of the probe and the return electrode is spaced from the active electrode and enclosed within an insulating sheath. This minimizes exposure of the return electrode to surrounding tissue and minimizes possible shorting of the current between the active and return electrodes. In oral procedures, the probe may be introduced directly into the cavity of the open mouth so that the active electrode is positioned against gingival or mucosal tissue. In laparoscopic procedures, the probe will typically be passed through a conventional trocar cannula while viewing of the operative site is provided through the use of a laparoscope disposed in a separate cannula.

The apparatus according to the present invention comprises an electrosurgical probe having a shaft with a proximal end, a distal end, and at least one active electrode at or near the distal end. A connector is provided at or near the proximal end of the shaft for electrically coupling the active electrode to a high frequency voltage source. A return electrode coupled to the voltage source is spaced a sufficient distance from the active electrode to substantially avoid or minimize current shorting therebetween and to shield the return electrode from tissue. The return electrode may be provided integral with the shaft of the probe or it may be separate from the shaft (e.g., on a liquid supply instrument). In both cases, the return electrode defines an inner passage

for flow of electrically conducting liquid therethrough. The liquid is directed through the return electrode and over the active electrode to thereby provide a return current flow path between the tissue target site and the return electrode.

In a preferred aspect of the invention, the active electrode comprises an electrode array having a plurality of electrically isolated electrode terminals disposed over a contact surface, which may be a planar or non-planar surface and which may be located at the distal tip or over a lateral surface of the shaft, or over both the tip and lateral surface(s). The electrode array will include at least two and preferably more electrode terminals, and may further comprise a temperature sensor. In a preferred aspect, each electrode terminal will be connected to the proximal connector by an electrically isolated conductor disposed within the shaft. The conductors permit independent electrical coupling of the electrode terminals to a high frequency power supply and control system with optional temperature monitor for operation of the probe. The control system preferably incorporate active and/or passive current limiting structures, which are designed to limit current flow when the associated electrode terminal is in contact with a low resistance return path back to the return electrode.

The use of such electrode arrays in electrosurgical procedures is particularly advantageous as it has been found to limit the depth of tissue necrosis without substantially reducing power delivery and ablation rates. The voltage applied to each electrode terminal causes electrical energy to be imparted to any body structure which is contacted by, or comes into close proximity with, the electrode terminal, where a current flow through all low electrical impedance paths is preferably but not necessarily limited. It will be appreciated that such low impedance paths generally occur when an electrode terminal does not contact or come into close proximity with the body structure, but rather is in contact with a low impedance environment, such as the saline, or other electrolyte being introduced past the return electrode. The presence of an electrolyte provides a relatively low impedance path back to the common or return electrode.

The apparatus and method of the present invention provide a number of advantages, particularly in respect to the ablation or cutting of tissue. The ability to control current flow through individual electrode terminals minimizes power dissipation into the surrounding medium. Limited power dissipation, in turn, permits the use of electrolytic irrigants, such as isotonic saline, to create a current flow path between the active electrode terminals and the return electrode. The isotonic saline may also be used to simultaneously irrigate the surgical site, which provides a number of well known physiological advantages. In addition, the ability to operate in a bipolar or quasi-bipolar mode reduces the risk of unwanted electrical stimulation from return current flowing through the patient's body, which can cause muscle spasms and can limit the depth of tissue necrosis during ablative resection.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the electrosurgical system including an electrosurgical probe, an electrically conducting liquid supply and an electrosurgical power supply constructed in accordance with the principles of the present invention;

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FIG. 2A is an enlarged, cross-sectional view of the distal tip of the electrosurgical probe of FIG. 1 illustrating an electrode arrangement suitable for rapid cutting and ablation of tissue structures;

FIG. 2B is an enlarged end view of the distal tip of the electrosurgical probe of FIG. 1;

FIG. 2C is a cross-sectional view of the proximal end of the electrosurgical probe, illustrating an arrangement for coupling the probe to the electrically conducting liquid supply of FIG. 1;

FIG. 3 is a detailed cross-sectional view of an alternative embodiment of the electrosurgical probe of FIG. 1;

FIG. 4 is an end view of the distal end of the electrosurgical probe of FIG. 3;

FIG. 5 is an end view of another embodiment of the electrosurgical probe of FIG. 1;

FIG. 6 is a partial cross-sectional side view of a further embodiment of the electrosurgical probe with the electrode array disposed transversely to the axis of the probe;

FIG. 7 is a partial front cross-sectional view of an electrosurgical probe and an electrically conductive liquid supply shaft illustrating use of the probe and the shaft in ablating target tissue;

FIG. 8 is an enlarged, cross-sectional view of the distal tip of yet another embodiment of the electrosurgical probe of FIG. 1;

FIG. 9 is a detailed end view of the probe of FIG. 8;

FIG. 10 is a side view of an electrosurgical probe having a shaft with an angled distal portion;

FIG. 11 is a side view of an electrosurgical probe having a shaft with a perpendicular distal portion;

FIG. 12 is a schematic view of an electrosurgical probe having two screwdriver-shaped electrodes extending from the distal end;

FIG. 13 is an end view of the probe of FIG. 12; and

FIG. 14 illustrates use of the probe of FIG. 12 for the rapid cutting of tissue.

FIG. 15 illustrates another alternative electrode surface configuration for the electrosurgical probe of FIG. 1.

FIG. 16 illustrates a second alternative electrode surface configuration.

FIGS. 17 and 18 illustrate an electrosurgical probe having an electrode surface which can be transformed from a flat, circular array (FIG. 17) to an elongate, linear array (FIG. 18) suitable for use in surgical cutting.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides an apparatus and method for selectively applying electrical energy to a target location within a patient's body, such as solid tissue or the like, particularly including gingival tissues and mucosal tissues located in the mouth. In addition, tissues which may be treated by the system and method of the present invention include tumors, abnormal tissues, and the like. For convenience, the remaining disclosure will be directed specifically to the cutting, shaping or ablation of gingival or mucosal tissue in oral surgical procedures, but it will be appreciated that the system and method can be applied equally well to procedures involving other tissues of the body, as well as to other procedures including open surgery, laparoscopic surgery, thoracoscopic surgery, and other endoscopic surgical procedures.

The present invention uses an electrode array including a plurality of independently current-limited and/or power-

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controlled electrode terminals distributed over a distal contact surface of a probe to apply electrical energy selectively to the target tissue while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power dissipation into surrounding electrically conductive liquids, such as blood, normal saline, and the like.

The electrosurgical probe will comprise a shaft having a proximal end and a distal end which supports an electrode array near its distal end. The shaft may assume a wide variety of configurations, with the primary purpose being to mechanically support the electrode array and permit the treating physician to manipulate the array from a proximal end of the shaft. Usually, the shaft will be a narrow-diameter rod or tube, more usually having dimensions which permit it to be introduced into a body cavity, such as the mouth or the abdominal cavity, through an associated trocar or cannula in a minimally invasive procedure, such as arthroscopic, laparoscopic, thoracoscopic, and other endoscopic procedures. Thus, the shaft will typically have a length of at least 5 cm for oral procedures and at least 10 cm, more typically being 20 cm, or longer for endoscopic procedures. The shaft will typically have a diameter of at least 1 mm and frequently in the range from 1 to 10 mm. The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft. Specific shaft designs will be described in detail in connection with the figures hereinafter.

The circumscribed area of the electrode array is in the range from 0.25 mm² to 75 mm², preferably from 0.5 mm² to 40 mm², and will usually include at least two isolated electrode terminals, more usually at least four electrode terminals, preferably at least six electrode terminals, and often 50 or more electrode terminals, disposed over the distal contact surfaces on the shaft. By bringing the electrode array(s) on the contact surface(s) against or in close proximity with the target tissue and applying high frequency voltage between the array(s) and an additional common or return electrode in direct or indirect contact with the patient's body, the target tissue is selectively ablated or cut, permitting selective removal of portions of the target tissue while desirably minimizing the depth of necrosis to surrounding tissue. In particular, this invention provides a method and apparatus for effectively ablating and cutting tissue which may be located in close proximity to other critical organs, vessels or structures (e.g., teeth, bone) by simultaneously (1) causing electrically conducting liquid to flow between the common and active electrodes, (2) applying electrical energy to the target tissue surrounding and immediately adjacent to the tip of the probe, (3) bringing the active electrode(s) in contact or close proximity with the target tissue using the probe itself, and (4) optionally moving the electrode array axially and/or transversely over the tissue.

Each individual electrode terminal in the electrode array is electrically insulated from all other electrode terminals in the array within said probe and is connected to a power source which is isolated from each of the other electrodes in the array or to circuitry which limits or interrupts current flow to the electrode when low resistivity material (e.g.,

blood or electrically conductive saline irrigant) causes a lower impedance path between the common electrode and the individual electrode terminal. The isolated power sources for each individual electrode may be separate power supply circuits having internal impedance characteristics which limit power to the associated electrode terminal when a low impedance return path is encountered, may be a single power source which is connected to each of the electrodes through independently actuable switches or may be provided by independent current limiting elements, such as inductors, capacitors, resistors and/or combinations thereof.

The tip region of the probe is thus composed of many independent electrode terminals designed to deliver electrical energy in the vicinity of the tip. The selective application of electrical energy to of the target tissue is achieved by connecting each individual electrode terminal and the common electrode to a power source having independently controlled or current limited channels. The common electrode may be a tubular member of conductive material proximal to the electrode array at the tip which also serves as a conduit for the supply of the electrically conducting liquid between the active and common electrodes. The application of high frequency voltage between the common electrode and the electrode array results in the generation of high electric field intensities at the distal tips of the electrodes with conduction of high frequency current from each individual electrode terminal to the said common electrode. The current flow from each individual electrode terminal to the common electrode is controlled by either active or passive means, or a combination thereof, to deliver electrical energy to the target tissue while minimizing energy delivery to surrounding (non-target) tissue and any conductive fluids which may be present (e.g., blood, electrolytic irrigants such as saline, and the like).

In a preferred aspect, this invention takes advantage of the differences in electrical resistivity between the target tissue (e.g., gingiva, muscle, fascia, tumor or other connective tissue) and the surrounding conductive liquid (e.g., isotonic saline irrigant). By way of example, for any selected level of applied voltage, if the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is isotonic saline irrigant liquid (having a relatively low electrical impedance), the current control means connected to the individual electrode will limit current flow so that the heating of intervening conductive liquid is minimized. On the other hand, if a portion of or all of the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is gingival tissue (having a relatively higher electrical impedance), the current control circuitry or switch connected to the individual electrode will allow current flow sufficient for the deposition of electrical energy and associated ablation or electrical breakdown of the target tissue in the immediate vicinity of the electrode surface.

The application of a high frequency voltage between the common or return electrode and the electrode array for appropriate time intervals effects ablation, cutting or reshaping of the target tissue. The tissue volume over which energy is dissipated (i.e., a high voltage gradient exists) may be precisely controlled, for example, by the use of a multiplicity of small electrodes whose effective diameters range from about 2 mm to 0.01 mm, preferably from about 1 mm to 0.05 mm, and more preferably from about 0.5 mm to 0.1 mm. Electrode areas for both circular and non-circular terminals will have a contact area (per electrode) below 5 mm², preferably being in the range from 0.0001 mm² to 1 mm².

and more preferably from 0.005 mm² to 0.5 mm². The use of small diameter electrode terminals increases the electric field intensity and reduces the extent or depth of tissue necrosis as a consequence of the divergence of current flux lines which emanate from the exposed surface of each electrode terminal. Energy deposition in tissue sufficient for irreversible damage (i.e., necrosis) has been found to be limited to a distance of about one-half to one electrode diameter. This is a particular advantage over prior electro-surgical probes employing single and/or larger electrodes where the depth of tissue necrosis may not be sufficiently limited.

In previous electrosurgical devices, increased power application and ablation rates have been achieved by increasing the electrode area. Surprisingly, with the present invention, it has been found that the total electrode area can be increased (to increase power delivery and ablation rate) without increasing the depth of necrosis by providing multiple small electrode terminals. Preferably, the terminals will be spaced apart by a distance in the range from about one-half diameter to one diameter for optimum power delivery, as discussed below. The depth of necrosis may be further controlled by switching the applied voltage off and on to produce pulses of current, the pulses being of sufficient duration and associated energy density to effect ablation and/or cutting while being turned off for periods sufficiently long to allow for thermal relaxation between energy pulses. In this manner, the energy pulse duration and magnitude and the time interval between energy pulses are selected to achieve efficient rates of tissue ablation or cutting while allowing the temperature of the treated zone of tissue to "relax" or return to normal physiologic temperatures (usually to within 10° C. of normal body temperature [37° C.], preferably to within 5° C.) before the onset of the next energy (current) pulse.

The rate of energy delivery to the target tissue is controlled by the applied voltage level and duty cycle of the voltage pulse. The use of high frequency current minimizes induced stimulation of muscle tissue or nerve tissue in the vicinity of the body structure being treated. In addition, high frequencies minimize the risk of interfering with the natural pacing of the heart in circumstances where the probe of the present invention is used near the heart.

The power applied to the common electrode and the electrode array will be at high or radio frequency, typically between about 20 kHz and 20 MHz, usually being between about 30 kHz and 2 MHz, and preferably being between about 50 kHz and 400 kHz. The RMS (root mean square) voltage applied will usually be in the range from about 5 volts to 1000 volts, preferably being in the range from about 50 volts to 800 volts, and more preferably being in the range from about 10 volts to 500 volts. Usually, the current level will be selectively limited or controlled and the voltage applied will be independently adjustable, frequently in response to the resistance of tissues and/or fluids in the pathway between an individual electrode and the common electrode. Also, the applied current level may be in response to a temperature control means which maintains the target tissue temperature with desired limits at the interface between the electrode arrays and the target tissue. The desired surface temperature along a propagating surface just beyond the region of ablation will usually be in the range from about 40° C. to 100° C., and more usually from about 50° C. to 60° C. The tissue being ablated immediately adjacent the electrode array may reach even higher temperatures.

The preferred power source of the present invention delivers a high frequency current selectable to generate

average power levels ranging from tens of milliwatts to tens of watts per electrode, depending on the target tissue being ablated, the rate of ablation desired or the maximum allowed temperature selected for the probe tip. The power source allows the user to select the current level according to the specific requirements of a particular oral surgery, open surgery or other endoscopic surgery procedure.

The power source will be current limited or otherwise controlled so that undesired heating of electrically conductive fluids or other low electrical resistance media does not occur. In a presently preferred embodiment of the present invention, current limiting inductors are placed in series with each independent electrode terminal, where the inductance of the inductor is in the range of 20 μ H to 5000 μ H, depending on the electrical properties of the target tissue, the desired ablation rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in co-pending PCT application No. PCT/US94/05168, which has already been incorporated herein by reference. Additionally, current limiting resistors may be selected having a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual electrode in contact with a low resistance medium (e.g., saline irrigant), the resistance of the current limiting resistor increases significantly, thereby minimizing the power delivery from said electrode into the low resistance medium (e.g., saline irrigant).

As an alternative to such passive circuit structures, regulated current flow to each electrode terminal may be provided by a multi-channel power supply. A substantially constant current level for each individual electrode terminal within a range which will limit power delivery through a low resistance path, e.g., isotonic saline irrigant, would be selected by the user to achieve the desired rate of cutting or ablation. Such a multi-channel power supply thus provides a substantially constant current source with selectable current level in series with each electrode terminal, wherein all electrodes will operate at or below the same, user selectable maximum current level. Current flow to all electrode terminals could be periodically sensed and stopped if the temperature measured at the surface of the electrode array exceeds user selected limits. Particular control system designs for implementing this strategy are well within the skill of the art.

Yet another alternative involves the use of one or several power supplies which allow one or several electrodes to be simultaneously energized and which include active control means for limiting current levels below a preselected maximum level. In this arrangement, only one or several electrodes would be simultaneously energized for a brief period. Switching means would allow the next one or several electrodes to be energized for a brief period. By sequentially energizing one or several electrodes, the interaction between adjacent electrodes can be minimized (for the case of energizing several electrode positioned at the maximum possible spacing within the overall envelope of the electrode array) or eliminated (for the case of energizing only a single electrode at any one time). As before, a resistance measurement means may be employed for each electrode prior to the application of power wherein a (measured) low resistance (below some preselected level) will prevent that electrode from being energized during given cycle. By way of example, the sequential powering and control scheme of the present invention would function in a manner similar to an automobile distributor. In this example, an electrical contact rotates past terminals connected to each spark plug. In this

example, each spark plug corresponds to the exposed surface of each of the electrodes. In addition, the present invention includes the means to measure the resistance of the medium in contact with each electrode and cause voltage to be applied only if the resistance exceeds a preselected level.

The electrode array is formed over a contact surface on the shaft of the electrosurgical probe. The common (return) electrode surface will be recessed relative to the distal end of the probe and may be recessed within the conduit provided for the introduction of electrically conducting liquid to the site of the target tissue and array of active electrodes. In the exemplary embodiment, the shaft will be cylindrical over most of its length, with the contact surface being formed at the distal end of the shaft. In the case of laparoscopic or endoscopic applications, the contact surface may be recessed since it helps protect and shield the electrode terminals on the surface while they are being introduced, particularly while being introduced through the working channel of a trocar channel or a viewing scope.

The area of the contact surface can vary widely, and the contact surface can assume a variety of geometries, with particular areas in geometries being selected for specific applications. Electrode array contact surfaces can have areas in the range from 0.25 mm^2 to 50 mm^2 , usually being from 1 mm^2 to 20 mm^2 . The geometries can be planar, concave, convex, hemispherical, conical, or virtually any other regular or irregular shape. Most commonly, the electrode arrays will be formed at the distal tip of the electrosurgical probe shaft, frequently being planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures or being linear arrays for use in cutting. Alternatively or additionally, the electrode arrays may be formed on lateral surfaces of the electrosurgical probe shaft (e.g., in the manner of a spatula), facilitating access to certain body structures in electrosurgical procedures.

Referring to the drawings in detail, wherein like numerals indicate like elements, an electrosurgical system 11 is shown constructed according to the principles of the present invention. Electrosurgical system 11 generally comprises an electrosurgical probe 10 connected to a power supply 28 for providing high frequency voltage to a target tissue 52 and a liquid source 21 for supplying electrically conducting fluid 50 to probe 10.

In an exemplary embodiment as shown in FIG. 1, electrosurgical probe 10 includes an elongated shaft 13 which may be flexible or rigid, with flexible shafts optionally including support cannulas or other structures (not shown). Probe 10 includes a connector 19 at its proximal end and an array 12 of electrode terminals 58 disposed on the distal tip of shaft 13. A connecting cable 34 has a handle 22 with a connector 20 which can be removably connected to connector 19 of probe 10. The proximal portion of cable 34 has a connector 26 to couple probe 10 to power supply 28. The electrode terminals 58 are electrically isolated from each other and each of the terminals 58 is connected to an active or passive control network within power supply 28 by means of a plurality of individually insulated conductors 42 (see FIG. 2C). Power supply 28 has a selection means 30 to change the applied voltage level. Power supply 28 also includes means for energizing the electrodes 58 of probe 10 through the depression of a pedal 39 in a foot pedal 37 positioned close to the user. The foot pedal 37 may also include a second pedal (not shown) for remotely adjusting the energy level applied to electrodes 58. The specific design of a power supply which may be used with the electrosurgical probe of the present invention is described in parent application PCT/US94/05168, the full disclosure of which has previously been incorporated herein by reference.

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Referring to FIGS. 2A and 2B, the electrically isolated electrode terminals 58 are spaced-apart over an electrode array surface 82. The electrode array surface 82 and individual electrode terminals 58 will usually have dimensions within the ranges set forth above. In the preferred embodiment, the electrode array surface 82 has a circular cross-sectional shape with a diameter D (FIG. 2B) in the range from 1 mm to 10 mm. Electrode array surface 82 may also have an oval shape, having a length L in the range of 1 mm to 20 mm and a width W in the range from 0.5 mm to 7 mm, as shown in FIG. 5. The individual electrode terminals 58 will protrude over the electrode array surface 82 by a distance (H) from 0 mm to 2 mm, preferably from 0 mm to 1 mm (see FIG. 3). As described above, electrode terminals which are flush with the surface, or protrude by a minimum distance, will provide less aggressive ablation and are particularly suitable for smoothing of treated tissue surfaces and providing hemostasis to inhibit or prevent bleeding of treated surfaces.

The electrode terminals 58 are preferably composed of a refractory, electrically conductive metal or alloy, such as platinum, platinum alloys, titanium, titanium alloys and the like. Platinum is the preferred choice for electrode terminal material since it is biocompatible, has a low erosion rate, and can be readily fabricated and attached to conductors 42 within the shaft 13 of electrosurgical probe 10. As shown in FIG. 2B, the electrode terminals 58 are anchored in a support matrix 48 of suitable insulating material (e.g., ceramic or glass material, such as alumina, zirconia and the like) which could be formed at the time of manufacture in a flat, hemispherical or other shape according to the requirements of a particular procedure. The preferred support matrix material is alumina, available from Kyocera Industrial Ceramics Corporation, Elk Grove, Ill., because of its high thermal conductivity, good electrically insulative properties, high flexural modulus, resistance to carbon tracking, biocompatibility, and high melting point.

As shown in FIG. 2A, the support matrix 48 is adhesively joined to a tubular support member 78 that extends most or all of the distance between matrix 48 and the proximal end of probe 10. Tubular member 78 preferably comprises an electrically insulating material, such as an epoxy or silicone-based material. In a preferred construction technique, electrode terminals 58 extend through pre-formed openings in the support matrix 48 so that they protrude above electrode array surface 82 by the desired distance H (FIG. 3). The electrodes are then bonded to the distal surface 82 of support matrix 48, typically by an inorganic sealing material 80. Sealing material 80 is selected to provide effective electrical insulation, and good adhesion to both the alumina matrix 48 and the platinum or titanium electrode terminals. Sealing material 80 additionally should have a compatible thermal expansion coefficient and a melting point well below that of platinum or titanium and alumina or zirconia, typically being a glass or glass ceramic.

In the embodiment shown in FIGS. 2A and 2B, probe 10 includes a return electrode 56 for completing the current path between electrode terminals 58 and power supply 28. Return electrode 56 is preferably an annular member positioned around the exterior of shaft 13 of probe 10. Return electrode 56 may fully or partially circumscribe tubular support member 78 to form an annular gap 54 therebetween for flow of electrically conducting liquid 50 therethrough, as discussed below. Gap 54 preferably has a width in the range of 0.25 mm to 4 mm. Return electrode 56 extends from the proximal end of probe 10, where it is suitably connected to power supply 28 via connectors 19, 20, to a point slightly proximal of electrode array surface 82, typically about 1 mm to 10 mm.

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Return electrode 56 is disposed within an electrically insulative jacket 18, which is typically formed as one or more electrically insulative sheaths or coatings, such as polytetrafluoroethylene, polyamide, and the like. The provision of the electrically insulative jacket 18 over return electrode 56 prevents direct electrical contact between return electrode 56 and any adjacent body structure. Such direct electrical contact between a body structure (e.g., tendon) and an exposed common electrode member 56 could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis.

Return electrode 56 is preferably formed from an electrically conductive material, usually metal, which is selected from the group consisting of stainless steel, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. The return electrode 56 may be composed of the same metal or alloy which forms the electrode terminals 58 to minimize any potential for corrosion or the generation of electrochemical potentials due to the presence of dissimilar metals contained within an electrically conductive fluid 50, such as isotonic saline (discussed in greater detail below).

As shown in FIG. 2A, return electrode 56 is not directly connected to electrode terminals 58. To complete this current path so that terminals 58 are electrically connected to return electrode 56 via target tissue 52, electrically conducting liquid 50 (e.g., isotonic saline) is caused to flow along liquid paths 83. Liquid paths 83 are formed by annular gap 54 between outer return electrode 56 and tubular support member 78 and an inner lumen 57 within an inner tubular member 59. The electrically conducting liquid 50 flowing through fluid paths 83 provides a pathway for electrical current flow between target tissue 52 and return electrode 56, as illustrated by the current flux lines 60 in FIG. 2A. When a voltage difference is applied between electrode array 12 and return electrode 56, high electric field intensities will be generated at the distal tips of terminals 58 with current flow from array 12 through the target tissue to the return electrode, the high electric field intensities causing ablation of tissue 52 in zone 88.

FIGS. 2C, 3 and 4 illustrate an alternative embodiment of electrosurgical probe 10 which has a return electrode 55 positioned within tubular member 78. Return electrode 55 is preferably a tubular member defining an inner lumen 57 for allowing electrically conducting liquid 50 (e.g., isotonic saline) to flow therethrough in electrical contact with return electrode 55. In this embodiment, a voltage difference is applied between electrode terminals 58 and return electrode 55 resulting in electrical current flow through the electrically conducting liquid 50 as shown by current flux lines 60 (FIG. 3). As a result of the applied voltage difference and concomitant high electric field intensities at the tips of electrode terminals 58, tissue 52 becomes ablated or transected in zone 88.

FIG. 2C illustrates the proximal or connector end 70 of probe 10 in the embodiment of FIGS. 3 and 4. Connector 19 comprises a plurality of individual connector pins 74 positioned within a housing 72 at the proximal end 70 of probe 10. Electrode terminals 58 and the attached insulating conductors 42 extend proximally to connector pins 74 in connector housing 72. Return electrode 55 extends into housing 72, where it bends radially outward to exit probe 10. As shown in FIGS. 1 and 2C, a liquid supply tube 15 removably couples liquid source 21, (e.g., a bag of fluid elevated above the surgical site or having a pumping device), with return electrode 55. Preferably, an insulating jacket 14 covers the exposed portions of electrode 55. One of the connector pins

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76 is electrically connected to return electrode 55 to couple electrode 55 to power supply 28 via cable 34. A manual control valve 17 may also be provided between the proximal end of electrode 55 and supply tube 15 to allow the surgical team to regulate the flow of electrically conducting liquid 50.

FIG. 6 illustrates another embodiment of probe 10 where the distal portion of shaft 13 is bent so that electrode terminals extend transversely to the shaft. Preferably, the distal portion of shaft 13 is perpendicular to the rest of the shaft so that electrode array surface 82 is generally parallel to the shaft axis, as shown in FIG. 6. In this embodiment, return electrode 55 is mounted to the outer surface of shaft 13 and is covered with an electrically insulating jacket 18. The electrically conducting fluid 50 flows along flow path 83 through return electrode 55 and exits the distal end of electrode 55 at a point proximal of electrode surface 82. The fluid is directed exterior of shaft to electrode surface 82 to create a return current path from electrode terminals 58, through target tissue 52, to return electrode 55, as shown by current flux lines 60.

FIG. 7 illustrates another embodiment of the invention where electrosurgical system 11 further includes a liquid supply instrument 64 for supplying electrically conducting fluid 50 between electrode terminals 58 and return electrode 55. Liquid supply instrument 64 comprises an inner tubular member or return electrode 55 surrounded by an electrically insulating jacket 18. Return electrode 55 defines an inner passage 83 for flow of fluid 50. As shown in FIG. 7, the distal portion of instrument 64 is preferably bent so that liquid 50 is discharged at an angle with respect to instrument 64. This allows the surgical team to position liquid supply instrument 64 adjacent electrode surface 82 with the proximal portion of supply instrument 64 oriented at a similar angle to probe 10.

FIGS. 8 and 9 illustrate another embodiment of probe 10 where the return electrode is an outer tubular member 56 that circumscribes support member 78 and conductors 42. Insulating jacket 18 surrounds tubular member 56 and is spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 9). Annular gap preferably has a width in the range of 0.25 mm to 4 mm. Ribs 96 can be formed on either the jacket 18 or member 56. The distal end of return electrode 56 is a distance L_1 from electrode surface 82. Distance L_1 is preferably about 0.5 to 10 mm and more preferably about 1 to 10 mm.

As shown in FIG. 8, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with the return electrode) and is discharged through the distal end of gap 54. The liquid 50 is then directed around support member 78 to electrode terminals 58 to provide the current pathway between the electrode terminals and return electrode 56. Since return electrode 56 is proximally recessed with respect to electrode surface 82, contact between the return electrode 56 and surrounding tissue is minimized. In addition, the distance L_1 between the active electrode terminals 58 and the return electrode 56 reduces the risk of current shorting therebetween.

The present invention is not limited to an electrode array disposed on a relatively planar surface at the distal tip of probe 10, as described above. Referring to FIGS. 12-14, an alternative probe 10 includes a pair of electrodes 58a, 58b mounted to the distal end of shaft 13. Electrodes 58a, 58b are electrically connected to power supply as described above and preferably have tips 100a, 100b with a screwdriver shape. The screwdriver shape provides a greater

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amount of "edges" to electrodes 58a, 58b, to increase the electric field intensity and current density at the edges and thereby improve the cutting ability as well as the ability to limit bleeding from the incised tissue (i.e., hemostasis).

As shown in FIG. 12, current flows between electrode tips 100a and 100b as indicated by current flux lines 60 to heat the target tissue 52. The surgical team then moves probe 10 transversely across tissue 52 to effect an incision 102 in tissue 52, as shown in FIG. 14.

Other modifications and variations can be made to disclose embodiments without departing from the subject invention as defined in the following claims. For example, shaft 13 of probe 10 may have a variety of configurations other than the generally linear shape shown in FIGS. 1-8. For example, shaft 13 may have a distal portion that is angled, in the range of 10° to 30° (FIG. 10) or 90° (FIGS. 11 and 6), to improve access to the operative site of the tissue 52 being ablated or cut (see FIG. 10). A shaft having a 90° bend angle may be particular useful for accessing gingiva located in the back portion of the patient's mouth and a shaft having a 10° to 30° bend angle may be useful for accessing gingiva near or in the front of the patient's mouth.

Yet another configuration for tip 200 of probe 10 is shown in FIG. 15 wherein a concave or wedge-shaped arrangement of electrodes 58 is provided to facilitate good contact with target tissue which can be embraced by said concave or wedge-shaped opening. As before, the return electrode 56 may be positioned proximal to probe tip 200.

Still yet another configuration for tip 200 of probe 10 is shown in FIG. 16 wherein electrodes 58 terminate on the side of the generally tubular (e.g., cylindrical) surface proximal to the distal end of probe 10. This configuration allows the electrode array to be brought into contact with target tissue surfaces which are tangent to the tubular surface of probe 10. As before, return electrode 56 may be positioned proximal to probe tip 200.

Another configuration for tip 200 of probe 10 is shown in FIGS. 17 and 18 and features a variable tip configuration which can be adjusted during the course of use of said probe 10. By way of example, tip 200 of probe 10 can be a cylindrical array of electrodes 58 which conforms to the cylindrical geometry of a rigid support member or cannula 202. The distal end of said cannula 202 may also serve as the common electrode 56 which is insulated in regions proximal to the tip region by an electrically insulating member 204. Referring now to FIG. 18, by extending the flexible array of electrodes 58 beyond the orifice of the cannula 202, an alternative electrode configuration can be obtained. By way of example, by placing a flat yet flexible member 206 between electrodes 58 as shown in FIG. 18, the electrode array can assume a flat "blade" shape configuration made up of a multiplicity of individual electrodes 58, each electrically insulated from all other electrodes. Such a configuration change may be advantageous if, after the insertion of the probe through a circular introduction port, the user can change the shape of the electrode array to achieve a flat "blade" shaped array whose width L_2 may be substantially greater than the circular electrode array configuration shown in FIG. 17. The increased width L_2 of the electrode array in FIG. 18 will provide the means for faster cutting through the target tissue since cutting depends primarily on the major dimension of the electrode array, either the diameter of the array (as shown in FIG. 17) or the width, L_2 , of the array (as shown in FIG. 18). If the array width in FIG. 18 is three times as greater as the array diameter in FIG. 17, then the rate of cutting of the target tissue can be increased by

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approximately a factor of three. An additional benefit is that the depth of necrosis in tissue on either side of the cut made with the flat electrode configuration will be less than with the larger array used in a circular configuration.

What is claimed is:

1. An electrosurgical system for use with a high frequency power supply and an electrically conducting fluid supply, the system comprising:

an electrosurgical probe comprising a shaft having a proximal end and a distal end, an electrode terminal disposed near the distal end, and a connector near the proximal end of the shaft for electrically coupling the electrode terminal to the electrosurgical power supply; a return electrode adapted to be electrically coupled to the electrosurgical power supply; and

a fluid delivery element defining a fluid path in electrical contact with the return electrode and the electrode terminal, the fluid path having an inlet adapted to be fluidly coupled to the electrically conducting fluid supply for directing fluid along the fluid path to generate a current flow path between the return electrode and the electrode terminal.

2. An electrosurgical system as in claim 1, wherein the return forms a portion of the shaft of the electrosurgical probe.

3. An electrosurgical system as in claim 2 further including an insulating member circumscribing the return electrode, the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and a body structure at the target site when the electrode terminal is positioned in close proximity or in partial contact with the body structure.

4. An electrosurgical system as in claim 2, wherein the return electrode is an inner tubular member and the fluid delivery element comprises an axial lumen within the return electrode, the axial lumen forming at least a portion of the fluid path and having an inlet in communication with the electrically conducting fluid supply and an outlet in fluid communication with the electrode terminal.

5. An electrosurgical system as in claim 2, wherein the return electrode is an outer tubular member, the shaft further comprising an insulating member, wherein the fluid delivery element comprises an axial passage between the insulating member and the return electrode, the axial passage forming at least a portion of the fluid path and having an inlet in communication with the electrically conducting fluid supply and an outlet in fluid and electrical communication with the electrode terminal.

6. An electrosurgical system as in claim 1 wherein the fluid delivery element comprises a fluid supply instrument separate from the electrosurgical probe, the return electrode forming a portion of the fluid supply instrument.

7. An electrosurgical system as in claim 6 wherein the return electrode is a tubular member defining an axial lumen therein, the axial lumen being electrically connected to the tubular member and having an inlet in communication with the fluid supply and an outlet for discharging the electrically conducting fluid towards the active electrode.

8. An electrosurgical system as in claim 7 wherein the fluid supply instrument comprises an electrically insulating sheath around the tubular member, the tubular member being proximally recessed from a distal end of the sheath.

9. An electrosurgical system as in claim 1 wherein the electrode terminal comprises an electrode array disposed near the distal end of the shaft, the array including a plurality of electrically isolated electrode terminals disposed over a contact surface.

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10. The electrosurgical system of claim 9 further comprising a plurality of current limiting elements each coupled to one of the electrode terminals for independently controlling current flow to each of the electrode terminals to inhibit power dissipation into the medium surrounding the target site.

11. The electrosurgical system of claim 9 further comprising means for independently controlling power to the electrode terminals based on the electrical impedance between each of the electrode terminals and the return electrode.

12. The electrosurgical system of claim 9 wherein the distal surface of the array of electrode terminals is circular in shape with a diameter in the range from 1 mm to 10 mm.

13. The electrosurgical system of claim 9 wherein the shape of the distal surface of the array of electrode terminals has an effective length of 1 mm to 20 mm and an effective width of 0.5 mm to 7.0 mm.

14. The electrosurgical system of claim 1 wherein the electrode terminal comprises a single active electrode disposed near the distal end of the shaft.

15. The electrosurgical system of claim 1 wherein the target site is selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.

16. The electrosurgical system of claim 1 further comprising a current limiting element for controlling current flow through the electrode terminal to inhibit power dissipation into the medium surrounding the target site.

17. The electrosurgical system of claim 16 wherein the electrically conducting fluid between the electrode terminal and the return electrode has an inherent capacitance, wherein the inherent capacitance of the tissue and electrically conducting fluid between the electrode terminal and the return electrode combined with the current limiting element together form a series resonant output circuit.

18. The system of claim 17 wherein the series resonant circuit has a resonant frequency that varies with changes in the inherent capacitance between the electrode terminal and the return electrode.

19. The electrosurgical system of claim 16 wherein the current limiting element is an active current limiting element for actively limiting current to the electrode terminal based on the electrical impedance between the electrode terminal and the return electrode.

20. The electrosurgical system of claim 19 wherein the active current limiting element measures current flow for a given applied voltage.

21. The electrosurgical system of claim 19 wherein the active current limiting element comprises an impedance sensor for indicating an electrical impedance less than a threshold level.

22. The electrosurgical system of claim 16 wherein the current limiting element is a passive current limiting element selected from the group consisting essentially of inductors, capacitors, resistors and combinations thereof.

23. The electrosurgical system of claim 1 wherein the height of the most distal portion of the electrode terminal relative to the most proximal portion of the electrode terminal exposed to the electrically conducting fluid is in the range from 0 to 2 mm.

24. The electrosurgical system of claim 1 wherein the distance between the most distal portion of the return electrode and the most proximal portion of the electrode terminal is in the range from 0.5 to 10 mm.

25. The electrosurgical system of claim 1 wherein the distal surface of the electrode terminal has a shape selected

from the group consisting essentially of flat, concave, convex, hemispherical, linear (in-line), pyramidal, conical and cylindrical.

26. The electrosurgical system of claim 1 wherein the fluid delivery element further comprises a control valve positioned on the shaft of the probe for controlling flow of the electrically conducting fluid through the fluid path.

27. The electrosurgical system of claim 1 further comprising means for controlling power to the electrode terminal based on the electrical impedance between the electrode terminal and the return electrode.

28. The electrosurgical system of claim 1 further comprising an insulating matrix surrounding and supporting the electrode terminal to electrically isolate a proximal portion of the electrode terminal from the electrically conducting fluid, the insulating matrix comprising an inorganic material.

29. The electrosurgical system of claim 28 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

30. The electrosurgical system of claim 1 wherein the electrode terminal and the return electrode are configured to effect the electrical breakdown of tissue in the immediate vicinity of the electrode terminal when high frequency voltage is applied between the electrode terminal and the return electrode in the presence of electrically conducting fluid.

31. The electrosurgical system of claim 1 wherein the electrically conducting fluid is selected from the group consisting essentially of blood and electrolytic irrigants.

32. The electrosurgical system of claim 1 wherein the electrically conducting liquid comprises saline.

33. The electrosurgical system of claim 1 wherein the electrode terminal has a distal portion configured for generating high electric field intensities sufficient to cause molecular disintegration of a body structure at the target site.

34. The electrosurgical system of claim 1 further comprising a temperature sensor adjacent the electrode terminal, the temperature sensor being adapted to be electrically coupled to the high frequency voltage source such that power delivery to the electrical terminal is limited if the measured temperature exceeds a threshold value.

35. The electrosurgical system of claim 34 wherein the temperature sensor is integral with the electrode terminal.

36. The electrosurgical system of 1 wherein the distal surface of the electrode terminal is circular in shape with a diameter in the range from 1 mm to 10 mm.

37. The electrosurgical system of claim 1 wherein the shape of the distal surface of the electrode terminal has an effective length of 1 mm to 20 mm and an effective width of 0.5 mm to 7.0 mm.

38. The system of claim 1 wherein the electrode terminal is configured for the cutting of tissue.

39. The system of claim 1 wherein the probe comprises a concave-shaped portion, the electrode terminal being disposed within the concave-shaped portion such that the concave-shaped portion at least partially surrounds the target site when the electrode terminal is brought into at least partial contact or close proximity with the target site.

40. The system of claim 1 wherein the probe comprises a lateral surface, the electrode terminal being positioned on the lateral surface such that the electrode terminal may be brought into at least partial contact or close proximity with the tissue surfaces which are substantially tangent to the electrosurgical probe.

41. The system of claim 1 wherein the electrode terminal and the return electrode are configured, upon the application

of sufficient voltage therebetween, to effect the ablation of tissue adjacent the electrode terminal such that a portion of said tissue is volumetrically removed.

42. The system of claim 1 wherein the electrode terminal is disposed at the distal tip of the electrosurgical probe.

43. The system of claim 42 wherein the return electrode is disposed proximally of the electrode terminal on the electrosurgical probe.

44. The system of claim 1 wherein the electrode terminal is a flexible electrode terminal disposed at the distal tip of the probe, the flexible electrode terminal being extendable relative to the distal tip of the probe.

45. An electrosurgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:

a high frequency power supply;

an electrosurgical probe comprising a shaft having a proximal end and a distal end, an electrode terminal disposed near the distal end, and a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply; a return electrode electrically coupled to the electrosurgical power supply; and

an electrically conducting fluid supply for directing electrically conducting fluid to the target site such that the electrically conducting fluid generates a current flow path between the return electrode and the electrode terminal.

46. An electrosurgical system as in claim 45, wherein the return electrode forms a portion of the shaft of the electrosurgical probe.

47. An electrosurgical system as in claim 46 further including an insulating member circumscribing the return electrode, the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and the patient's tissue.

48. An electrosurgical system as in claim 46, wherein the return electrode is an inner tubular member defining an axial lumen within the return electrode, the axial lumen having an inlet in communication with the electrically conducting fluid supply and an outlet in fluid communication with the electrode terminal.

49. An electrosurgical system as in claim 46, wherein the return electrode is an outer tubular member, the shaft further comprising an insulating member defining an axial passage between the insulating member and the return electrode, the axial passage having an inlet in communication with the electrically conducting fluid supply and an outlet in fluid and electrical communication with the electrode terminal.

50. An electrosurgical system as in claim 45 further including a fluid supply instrument separate from the electrosurgical probe, the return electrode forming a portion of the fluid supply instrument.

51. An electrosurgical system as in claim 50 wherein the return electrode is a tubular member defining an axial lumen therein, the axial lumen being electrically connected to the tubular member and having an inlet in communication with the fluid supply and an outlet for discharging the electrically conducting fluid towards the active electrode.

52. The electrosurgical system of claim 51 further comprising a plurality of current limiting elements each coupled to one of the electrode terminals for independent controlling current flow through the electrode terminals to inhibit power dissipation into the medium surrounding the target site.

53. An electrosurgical system as in claim 45 wherein the electrode terminal comprises an electrode array disposed near the distal end of the shaft, the array including a plurality

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of electrically isolated electrode terminals disposed over a contact surface.

54. The electrosurgical system of claim 53 further comprising means for independently controlling power to the electrode terminals based on the electrical impedance between each of the electrode terminals and the return electrode.

55. The electrosurgical system of claim 45 wherein the electrode terminal comprises a single active electrode disposed near the distal end of the shaft.

56. The electrosurgical system of claim 45 wherein the target site is selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.

57. The electrosurgical system of claim 45 further comprising a current limiting element for controlling current flow through the electrode terminal to inhibit power dissipation into the medium surrounding the target site.

58. The electrosurgical system of claim 45 wherein the frequency of the voltage applied between the return electrode and the electrode terminal is in the range of about 20 kHz and 20 Mhz.

59. The electrosurgical system of claim 45 wherein the voltage applied between the electrode terminal and the return electrode is in the range from 10 volts (RMS) to 1000 volts (RMS).

60. The electrosurgical system of claim 45 further comprising means for controlling power to the electrode terminal based on the electrical impedance between the electrode terminal and the return electrode.

61. The electrosurgical system of claim 45 further comprising an insulating matrix surrounding and supporting

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electrode terminal to electrically isolate a proximal portion of the electrode terminal from the electrically conducting fluid, the insulating matrix comprising an inorganic material.

62. The electrosurgical system of claim 45 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

63. An electrosurgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:

a high frequency power supply;

an electrosurgical probe comprising a shaft having a proximal end and a distal end, an electrode terminal disposed near the distal end, and a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply;

a return electrode electrically coupled to the electrosurgical power supply;

an electrically conducting fluid supply;

a fluid delivery element defining a fluid path electrically coupled to the electrode terminal for directing electrically conducting fluid to the target site and the electrode terminal to substantially surround the electrode terminal with electrically conducting fluid and to locate electrically conducting fluid between the electrode terminal and the target site.

64. The system of claim 63 wherein the return electrode is located on a surface of the patient's body.

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(54) **SYSTEMS AND METHODS FOR
ELECTROSURGICAL TISSUE TREATMENT
IN CONDUCTIVE FLUID**

4,033,351 7/1977 Hetzel 606/48
4,040,426 8/1977 Morrison, Jr. 128/303

(List continued on next page.)

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FOREIGN PATENT DOCUMENTS

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515 867 12/1992 (EP) A61B/17/36
0 597 463 5/1994 (EP) A61N5/04
0 703 461 A2 3/1996 (EP) G01R/27/02

(List continued on next page.)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 0 days.

OTHER PUBLICATIONS

This patent is subject to a terminal dis-
claimer.

V. E. Elsasser et al. *Acta Medico Technica* 24(4) :129-134
(1976).

M. Buechelt et al. *Lasers In Surgery and Medecine*
11:271-279 (1991).

J. Costello *Lasers in Surgery and Medecine* 12:121-124
(1992).

(List continued on next page.)

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Related U.S. Application Data

(62) Division of application No. 08/795,686, filed on Feb. 5,
1997, now Pat. No. 5,871,469, which is a division of
application No. 08/561,958, filed on Nov. 22, 1995, now Pat.
No. 5,697,882, which is a continuation-in-part of application
No. 08/485,219, filed on Jun. 7, 1995, now Pat. No. 5,697,
281, which is a continuation-in-part of application No.
08/446,767, filed as application No. PCT/US94/05168 on
May 10, 1994, now Pat. No. 5,697,909, which is a continu-
ation-in-part of application No. 08/059,681, filed on May 10,
1993, now abandoned, which is a continuation-in-part of
application No. 07/958,977, filed on Oct. 9, 1992, now Pat.
No. 5,366,443, which is a continuation-in-part of application
No. 07/817,575, filed on Jan. 7, 1992, now abandoned.

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(56) **References Cited**

U.S. PATENT DOCUMENTS

2,050,904 8/1936 Trice .

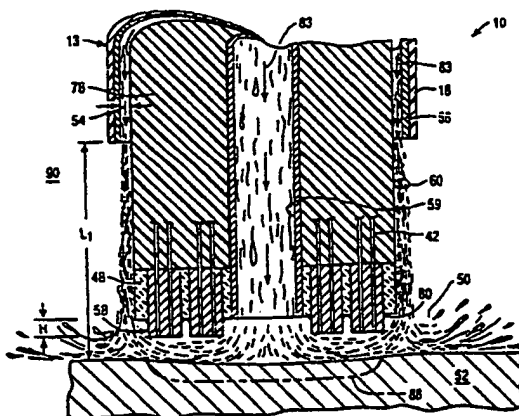
Primary Examiner—Lee Cohen

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(57) **ABSTRACT**

An electrosurgical probe (10) comprises a shaft (13) having
an electrode array (58) at its distal end and a connector (19)
at its proximal end for coupling the electrode array to a high
frequency power supply (28). The shaft includes a return
electrode (56) recessed from its distal end and enclosed
within an insulating jacket (18). The return electrode defines
an inner passage (83) electrically connected to both the
return electrode and the electrode array for passage of an
electrically conducting liquid (50). By applying high fre-
quency voltage to the electrode array and the return
electrode, the electrically conducting liquid generates a
current flow path between the return electrode and the
electrode array so that target tissue may be cut or ablated.
The probe is particularly useful in dry environments, such as
the mouth or abdominal cavity, because the electrically
conducting liquid provides the necessary return current path
between the active and return electrodes.

43 Claims, 17 Drawing Sheets



U.S. PATENT DOCUMENTS

4,043,342	8/1977	Morrison, Jr.	606/48	5,277,201	1/1994	Stern	607/98
4,116,198	9/1978	Roos	128/303	5,281,216	1/1994	Klicek	606/42
4,184,492	1/1980	Meinke et al.	128/303	5,281,218	1/1994	Imran	606/41
4,202,337	5/1980	Hren et al.	128/303	5,282,797	2/1994	Chess	606/9
4,228,800	10/1980	Degler, Jr. et al.	128/303	5,290,273	3/1994	Tan	606/9
4,232,676	11/1980	Herczog	128/303	5,290,282	3/1994	Casscells	606/29
4,240,441	12/1980	Khalil	128/692	5,300,069	4/1994	Hunsberger et al.	606/37
4,248,231	2/1981	Herczog et al.	128/303	5,300,099	4/1994	Rudie	607/101
4,326,529	4/1982	Doss	128/303.1	5,301,687	4/1994	Wong et al.	607/116
4,381,007	4/1983	Doss	128/303.1	5,304,170	4/1994	Green	606/9
4,476,862	10/1984	Pao	128/303.17	5,312,395	5/1994	Tan et al.	606/9
4,532,924	8/1985	Auth et al.	128/303.17	5,312,400	5/1994	Bales et al.	606/41
4,548,207	10/1985	Reimels	128/303	5,314,406	5/1994	Arias et al.	604/21
4,567,890	2/1986	Ohta et al.	128/303.13	5,318,563	6/1994	Malis et al.	606/38
4,593,691	6/1986	Lindstrom et al.	128/303.14	5,322,507	6/1994	Costello et al.	128/4
4,658,817	4/1987	Hardy	128/303	5,324,254	6/1994	Phillips	604/21
4,674,499	6/1987	Pao	128/303	5,326,343	7/1994	Rudie et al.	607/101
4,682,596	7/1987	Bales et al.	128/303	5,330,470	7/1994	Hagen	606/42
4,706,667	11/1987	Roos	128/303	5,330,518	7/1994	Neilson et al.	607/101
4,709,698	12/1987	Johnston et al.	128/303	5,334,140	8/1994	Phillips	604/35
4,727,874	3/1988	Bowers et al.	128/303	5,334,183	8/1994	Wuchinich	606/46
4,736,743	4/1988	Daikuzono	128/303.1	5,336,217	8/1994	Buyis et al.	606/9
4,737,678	4/1988	Hasegawa	313/36	5,336,220	8/1994	Ryan et al.	604/22
4,762,128	8/1988	Rosenbluth	128/343	5,342,357	8/1994	Nardella	606/40
4,765,331	8/1988	Petruzzi et al.	128/303	5,366,443	11/1994	Eggers et al.	604/114
4,785,806	11/1988	Deckelbaum	128/303.1	5,370,642	12/1994	Keller	606/9
4,813,429	3/1989	Eshel et al.	128/736	5,370,675	12/1994	Edwards et al.	607/101
4,823,791	4/1989	D'Amelio et al.	123/303	5,380,277	1/1995	Phillips	604/33
4,860,752	8/1989	Turner	128/422	5,380,316	1/1995	Aita et al.	606/7
4,931,047	6/1990	Broadwin et al.	604/22	5,383,876	1/1995	Nardella	606/49
4,936,301	6/1990	Rexroth et al.	606/45	5,383,917	1/1995	Desai et al.	607/702
4,943,290	7/1990	Rexroth et al.	606/45	5,389,096	2/1995	Aita et al.	606/15
4,955,377	9/1990	Lennox et al.	128/401	5,395,312	3/1995	Desai	604/22
4,967,765	11/1990	Turner et al.	128/785	5,417,687	5/1995	Nardella et al.	606/32
4,968,314	11/1990	Michaels	606/7	5,419,767	5/1995	Eggers et al.	604/114
4,976,711	12/1990	Parins et al.	606/48	5,423,803	6/1995	Tankovich	606/9
4,979,948	12/1990	Geddes et al.	606/33	5,432,882	7/1995	Jackman et al.	607/122
4,998,933	3/1991	Eggers et al.	606/41	5,441,499	8/1995	Fritzsche	606/45
5,007,437	4/1991	Sierzer	428/786	5,445,634	8/1995	Keller	606/9
5,007,908	4/1991	Rydell	606/47	5,454,809	10/1995	Janssen	606/41
5,009,656	4/1991	Reimels	606/48	5,496,312	3/1996	Klicek	606/34
5,035,696	7/1991	Rydell	606/47	5,514,130	5/1996	Baker	606/41
5,037,421	8/1991	Boutacoff et al.	606/15	5,556,397	9/1996	Long et al.	606/114
5,057,105	10/1991	Malone et al.	606/28	5,569,242	10/1996	Lax et al.	606/42
5,057,106	10/1991	Kasevich et al.	606/33	5,584,872	12/1996	LaFontaine et al.	607/116
5,061,266	10/1991	Hakky	606/15	5,609,151	3/1997	Mulier et al.	128/642
5,078,717	1/1992	Parins et al.	606/48	5,647,869	7/1997	Goble et al.	606/37
5,080,660	1/1992	Buelna	606/48	5,676,693	10/1997	LaFontaine	607/116
5,083,565	1/1992	Parins	128/642	5,681,282	10/1997	Eggers et al.	604/114
5,098,431	3/1992	Rydell	606/48	5,683,366	11/1997	Eggers et al.	604/114
5,102,410	4/1992	Dressel	606/15	5,697,281	12/1997	Eggers et al.	604/114
5,108,391	4/1992	Flachenecker et al.	606/38	5,697,536	12/1997	Eggers et al.	604/114
5,112,330	5/1992	Nishigaki et al.	606/46	5,697,882	12/1997	Eggers et al.	604/114
5,122,138	6/1992	Manwaring	606/46	5,697,909	12/1997	Eggers et al.	604/114
5,125,928	6/1992	Parins et al.	606/48	5,700,262	12/1997	Acosta et al.	606/48
5,147,354	9/1992	Boutacoff et al.	606/15	5,725,524	3/1998	Mulier et al.	606/41
5,151,098	9/1992	Loertscher	606/16	5,749,869	5/1998	Lindenmeier et al.	606/34
5,176,528	1/1993	Fry et al.	439/181	5,766,153	6/1998	Eggers et al.	604/114
5,178,620	1/1993	Eggers et al.	606/41	5,807,395	9/1998	Mulier et al.	606/41
5,190,517	3/1993	Zieve et al.	604/22	5,810,764	9/1998	Eggers et al.	604/23
5,192,280	3/1993	Parins	606/48	5,860,974	1/1999	Abele	606/41
5,195,959	3/1993	Smith	604/34	5,871,524	2/1999	Knowlton	607/101
5,197,963	3/1993	Parins	606/46	5,885,277	3/1999	Korth	606/35
5,217,455	6/1993	Tan	606/9	5,891,095	4/1999	Eggers et al.	604/114
5,217,457	6/1993	Delahuerga et al.	606/42	5,897,553	4/1999	Mulier et al.	606/114
5,249,585	10/1993	Turner et al.	607/99	5,902,272	5/1999	Eggers et al.	604/114
5,261,410	11/1993	Alfano et al.	128/664	5,944,715	8/1999	Goble et al.	606/41
5,267,994	12/1993	Gentelia et al.	606/15	6,004,319	12/1999	Goble et al.	606/48
5,267,997	12/1993	Farin et al.	606/38	6,013,076	1/2000	Goble et al.	606/41
5,273,524	12/1993	Fox et al.	604/21	6,015,406	1/2000	Goble et al.	606/41
				6,027,501	2/2000	Goble et al.	606/41

6,039,734 3/2000 Goble et al. 606/41
 6,056,746 5/2000 Goble et al. 606/48

FOREIGN PATENT DOCUMENTS

0 740 926 11/1996 (EP) A61B/17/39
 0 740 926 A2 11/1996 (EP) A61B/17/39
 0 754 437 1/1997 (EP) A61B/17/39
 2327350 1/1999 (GB) A61B/17/39
 2327351 1/1999 (GB) A61B/17/39
 2327352 1/1999 (GB) A61B/17/39
 57-57802 4/1982 (JP) A61B/1/100
 57-117843 7/1982 (JP) A61B/17/39
 WO 90/07303 7/1990 (WO) A61B/17/39
 WO 90/09303 7/1990 (WO) A61B/17/39
 91/13650 9/1991 (WO) A61N/5/04
 WO 92/21278 12/1992 (WO) A61B/5/04
 WO 93/13816 7/1993 (WO) A61B/17/36
 WO 93/20747 10/1993 (WO) A61N/1/06
 94/04220 3/1994 (WO) A61N/1/06
 94/08654 4/1994 (WO) A61M/37/00
 WO
 94/143863 7/1994 (WO) A61B/17/36
 94/26228 11/1994 (WO) A61G/17/36
 95/34259 12/1995 (WO) A61F/5/48
 96/00042 1/1996 (WO) A61B/17/39
 97/00646 1/1997 (WO) A61B/17/39
 97/00647 1/1997 (WO) A61B/17/39
 97/24073 7/1997 (WO) A61B/17/39

97/24993 7/1997 (WO) A61B/17/39
 97/24994 7/1997 (WO) A61B/17/39
 97/48346 12/1997 (WO) A61B/17/39
 WO 97/48345 12/1997 (WO) A61B/17/39
 98/27879 7/1998 (WO) A61B/17/36
 98/27880 7/1998 (WO) A61B/17/39
 99/51155 10/1999 (WO) A61B/17/36
 99/51158 10/1999 (WO) A61B/17/39

OTHER PUBLICATIONS

P. Nardella *SPIE* 1068:42-49 (1989).
 Rand et al. *J. Arthro. Surg.* 1:242-246 (1985).
 E.V. Kramolowsky et al. *J. of Urology* vol. 143, pp. 275-277 (1990).
 J.W. Ramsey et al. *Urological Research* vol. 13, pp. 99-102 (1985).
 R. Tucker et al., Abstract P14-11, p. 248, "A Bipolar Electrosurgical Turp Loop".
 R. Tucker et al. *J. of Urology* vol. 141, pp. 662-665, (1989).
 R. Tucker et al. *Urological Research* vol. 18, pp. 291-294 (1990).
 Pearce, John A. (1986) *Electrosurgery*, pp. 17, 69-75, 87, John Wiley & Sons, New York.
 Slager et al. *Z. Kardiol.* 76:Suppl. 6, 67-71 (1987).
 Slager et al. *JACC* 5(6):1382-6 (1985).

* cited by examiner

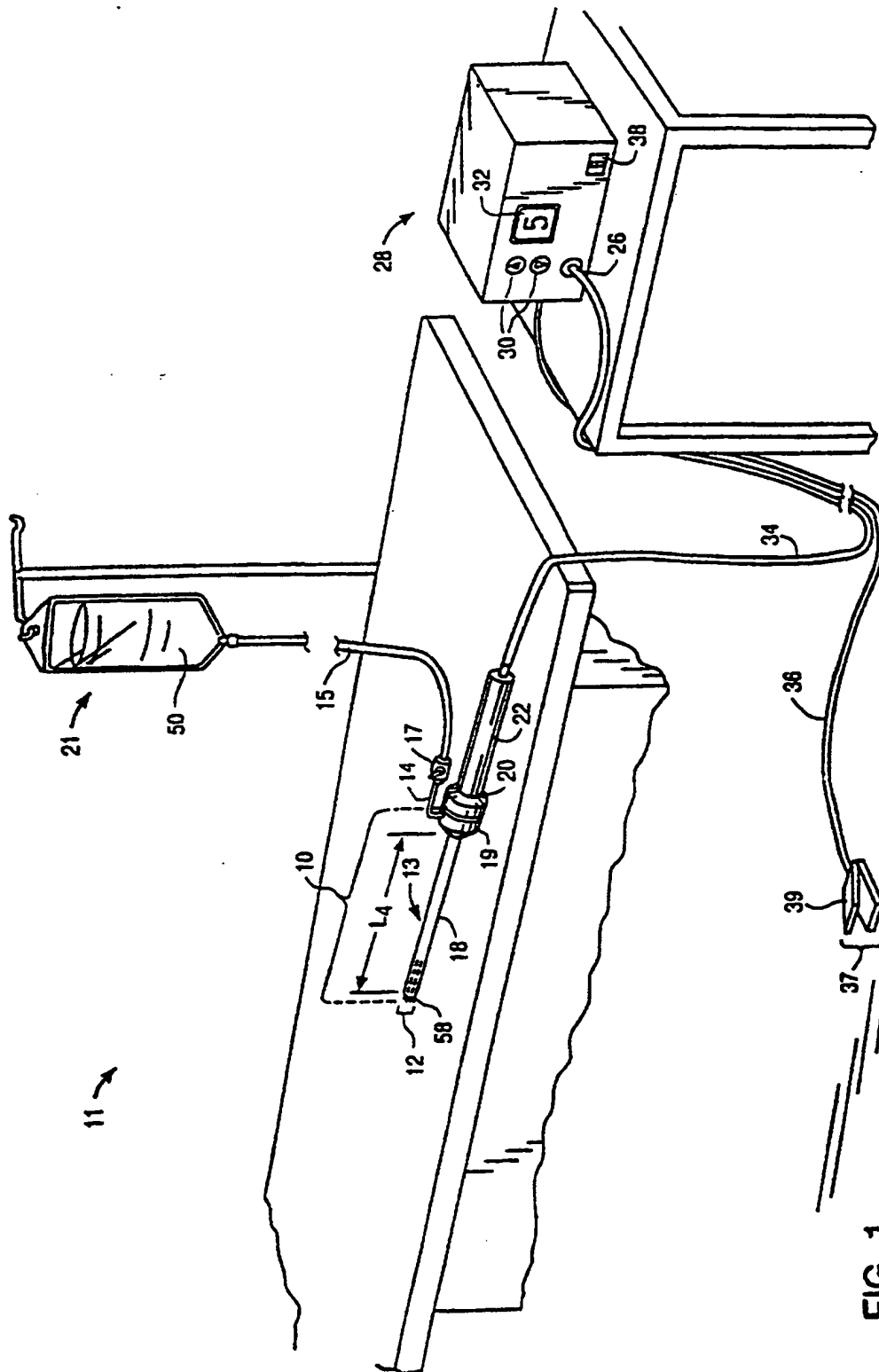


FIG. 1

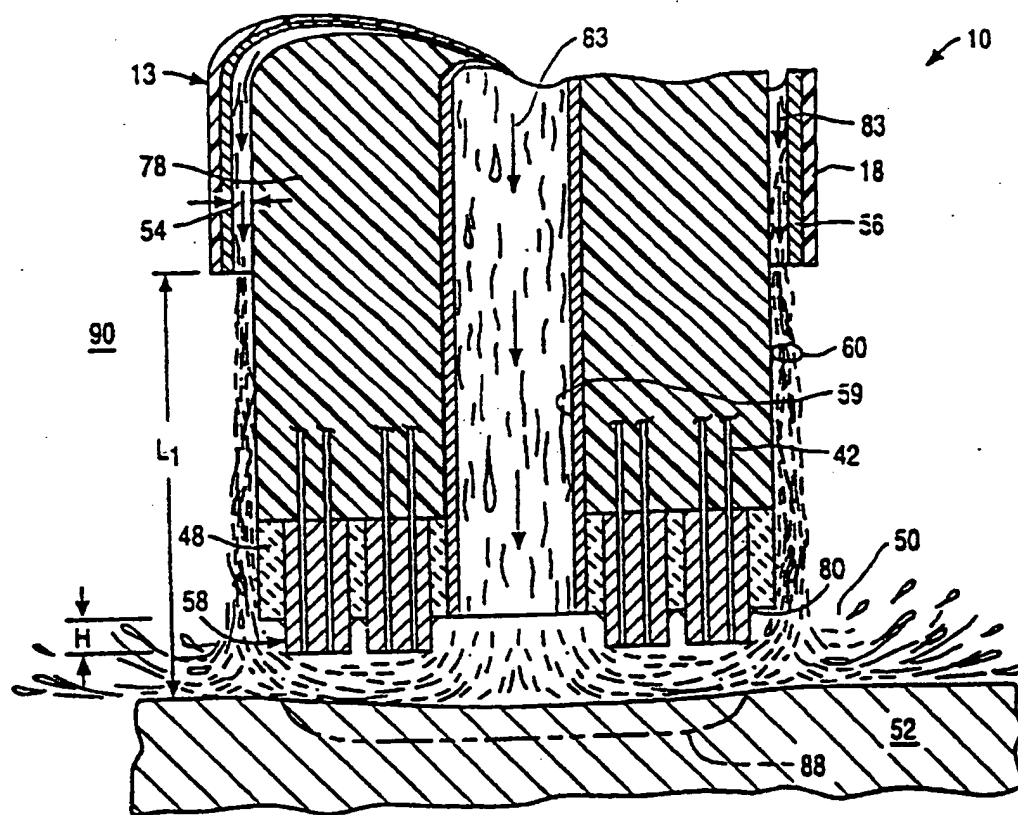


FIG. 2A

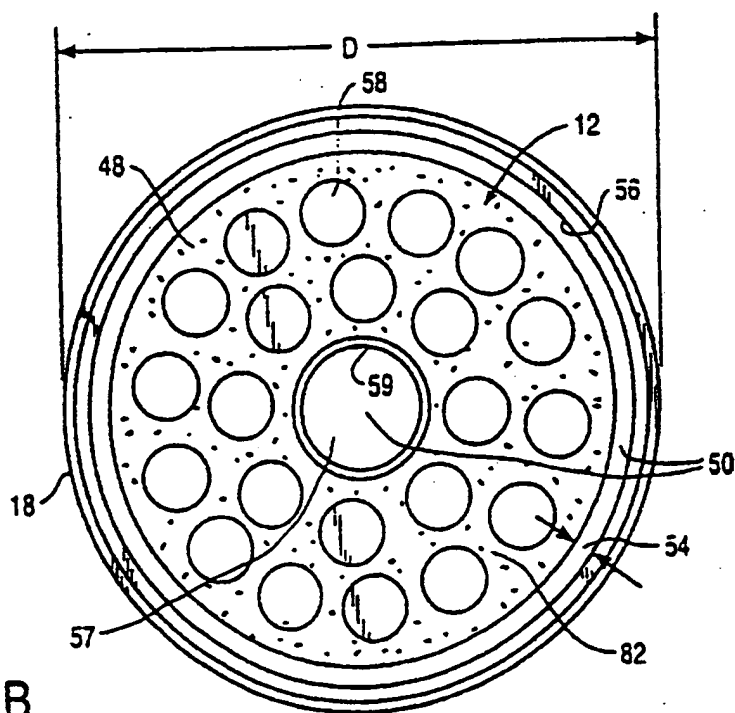


FIG. 2B

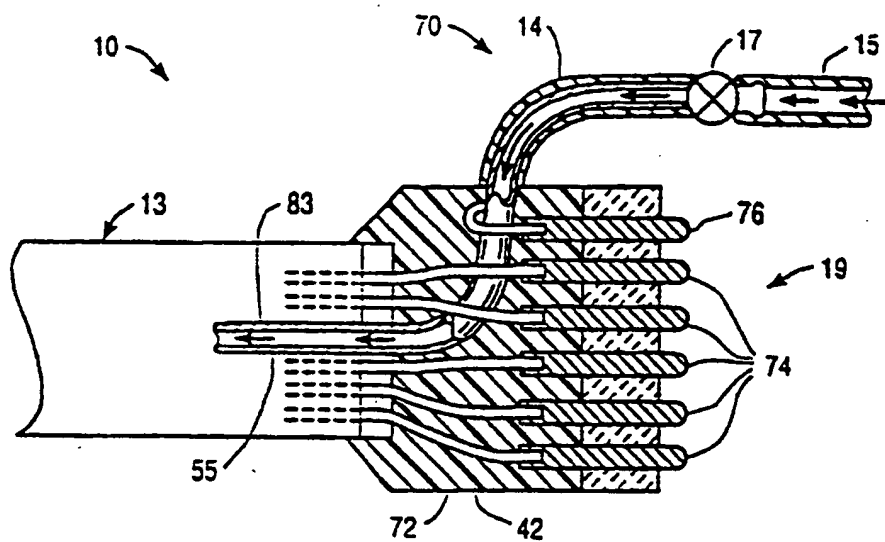


FIG. 2C

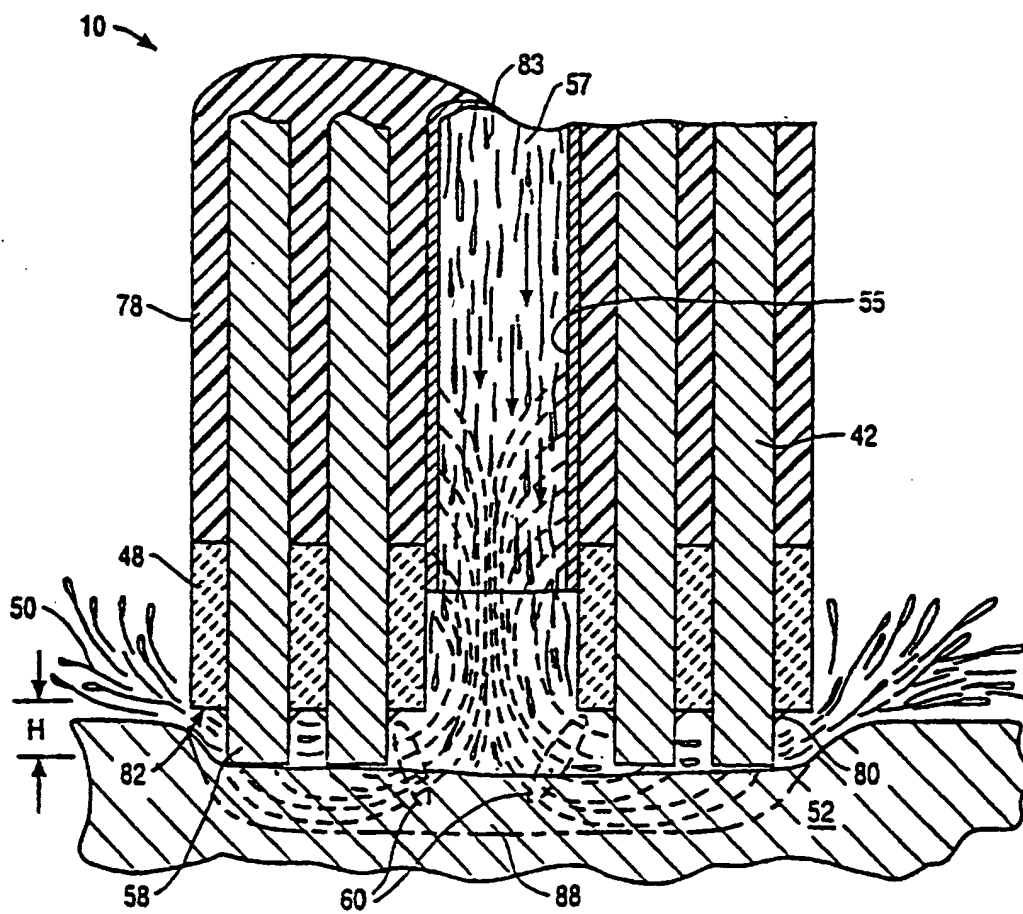


FIG. 3

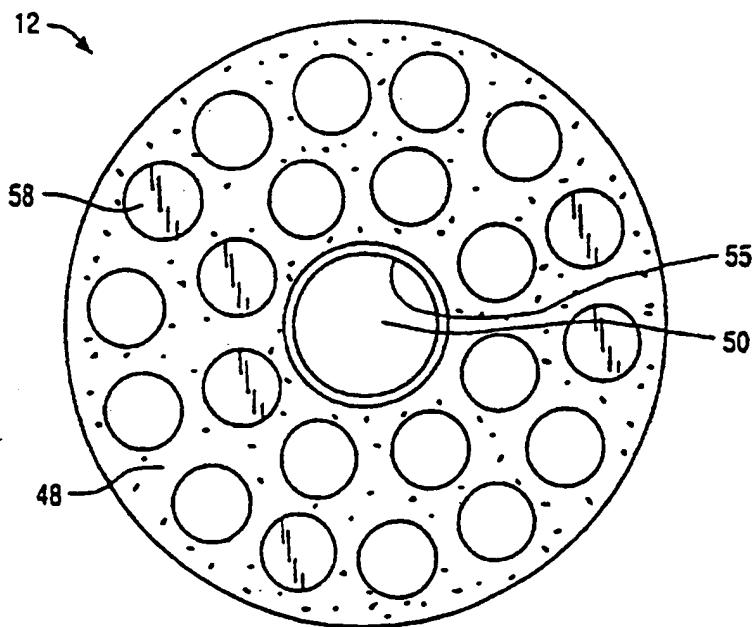


FIG. 4

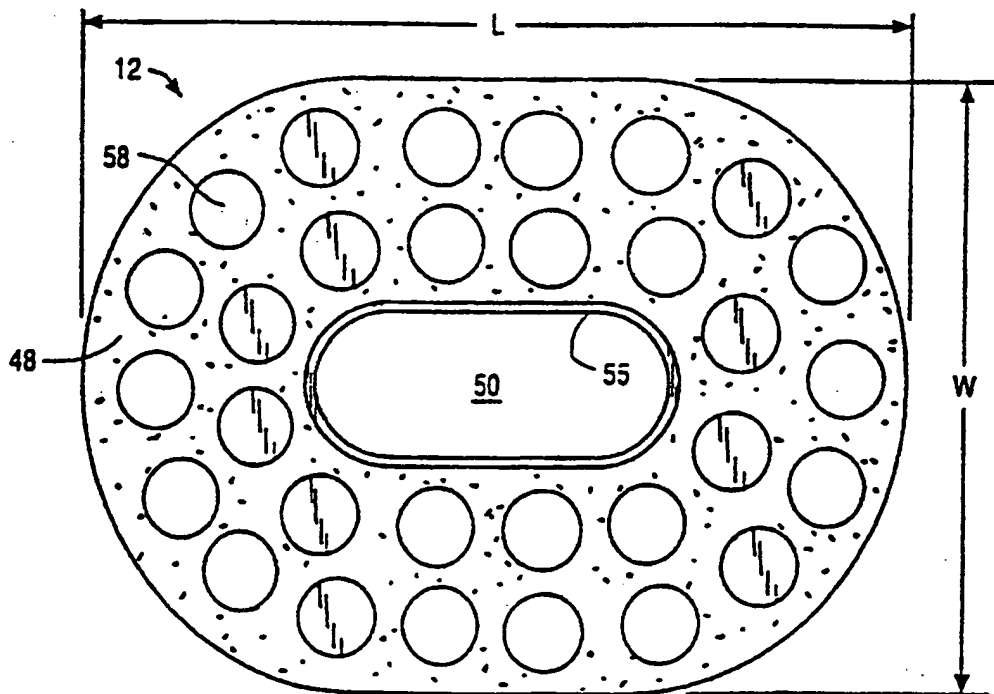


FIG. 5

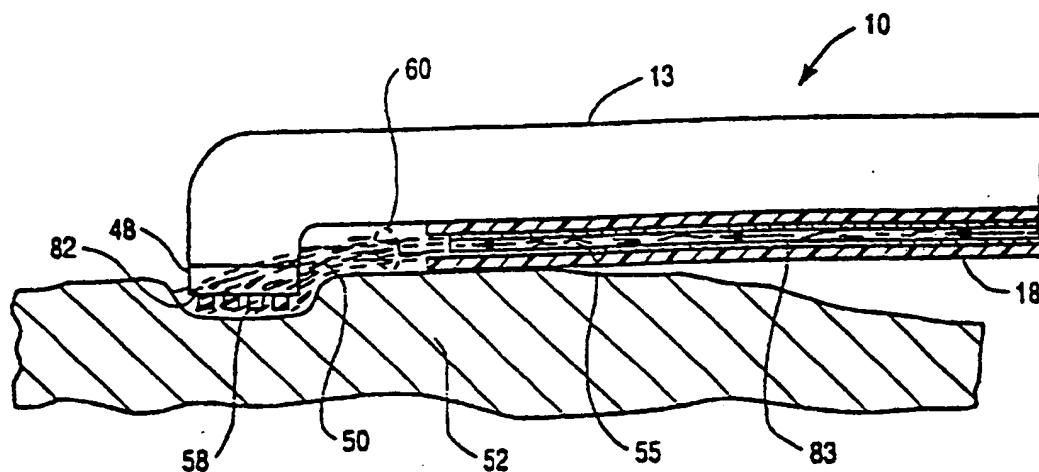


FIG. 6

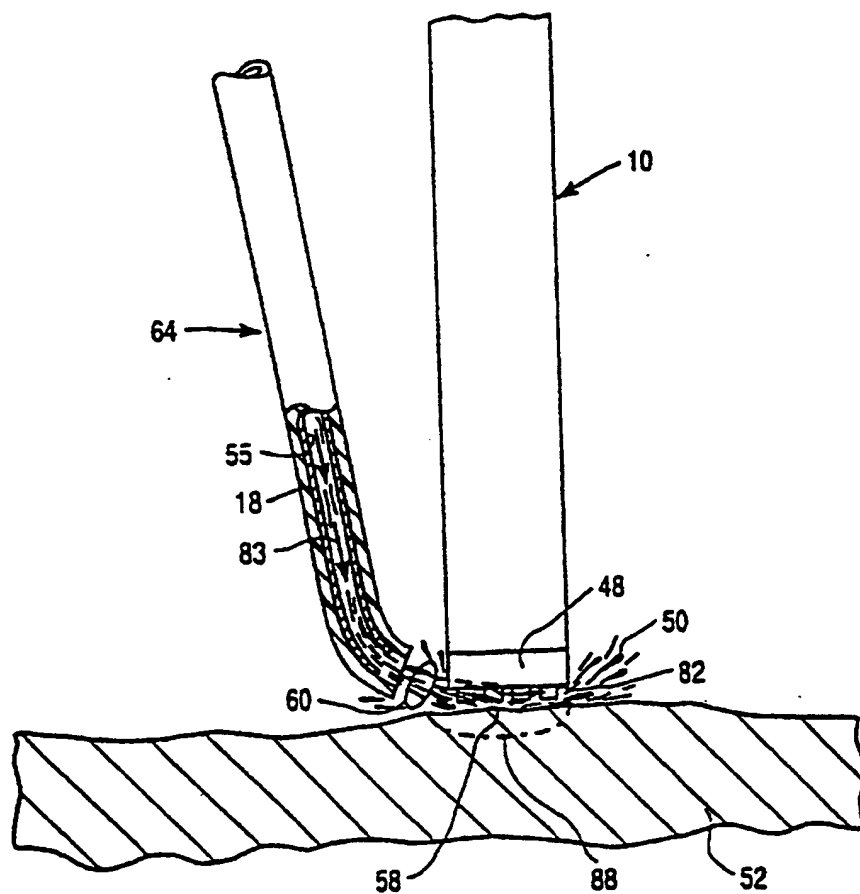


FIG. 7

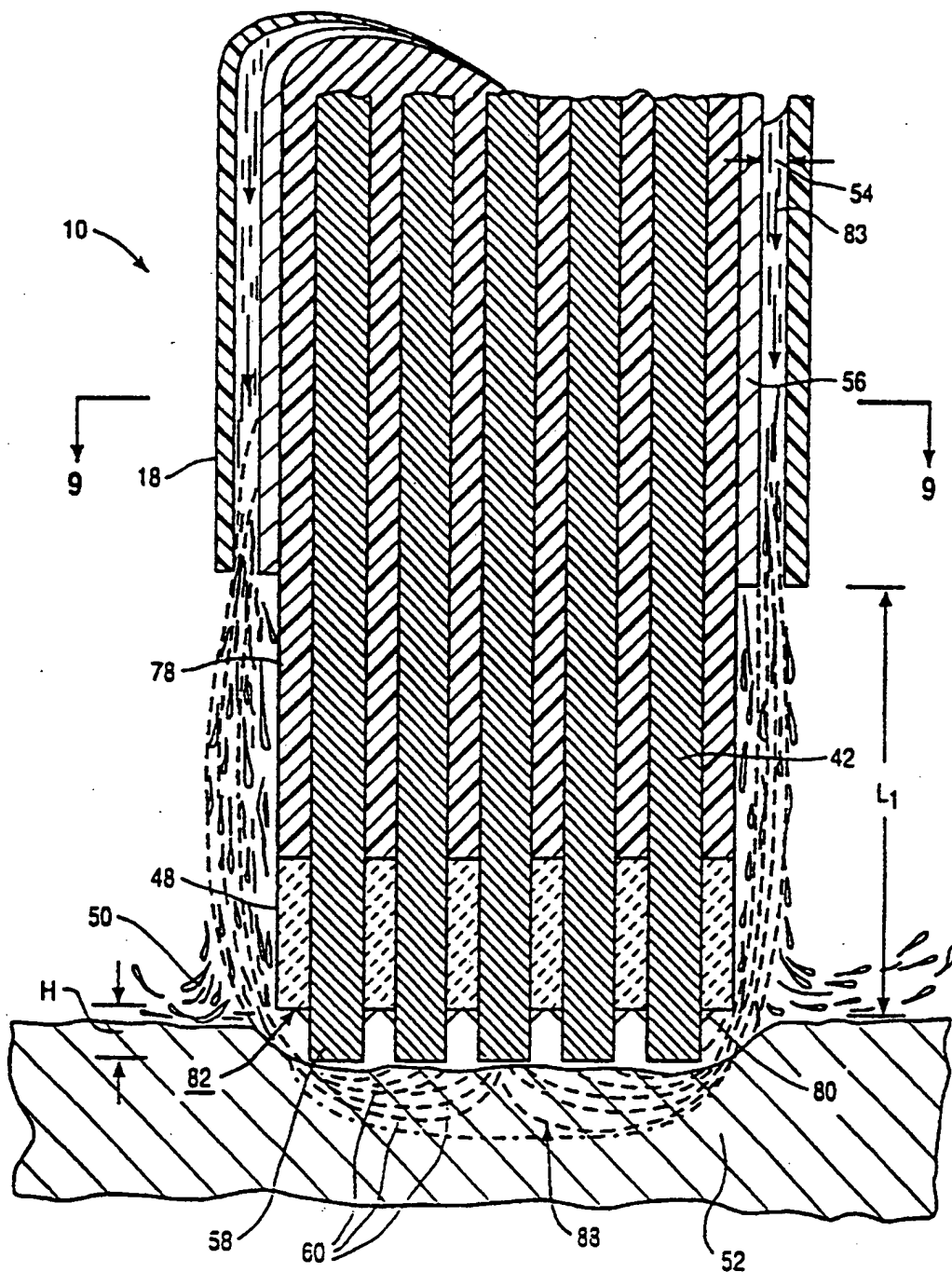


FIG. 8

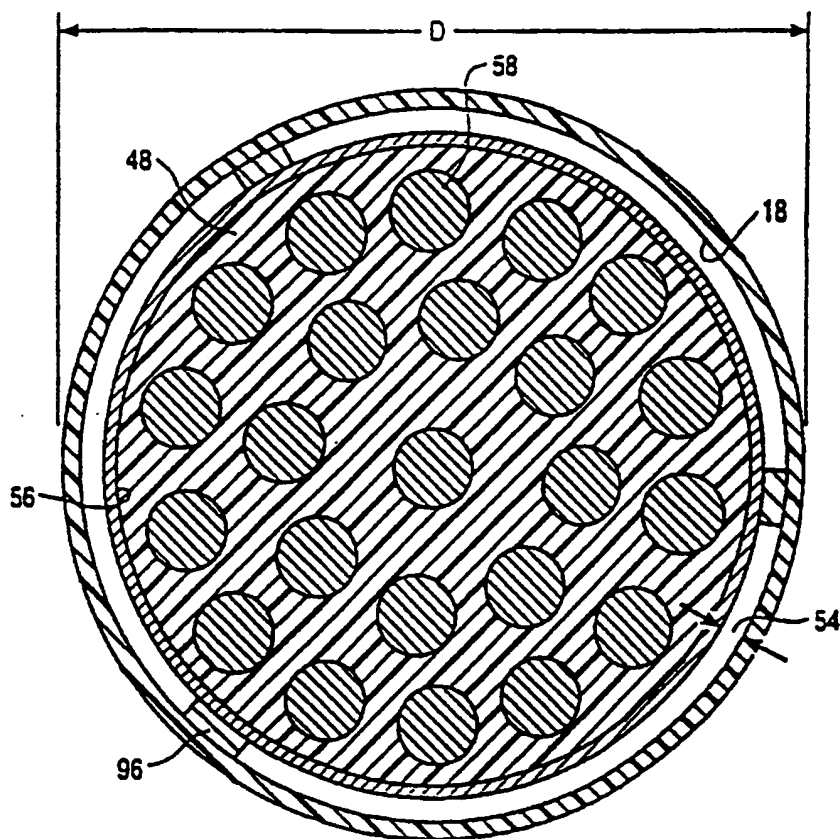


FIG. 9

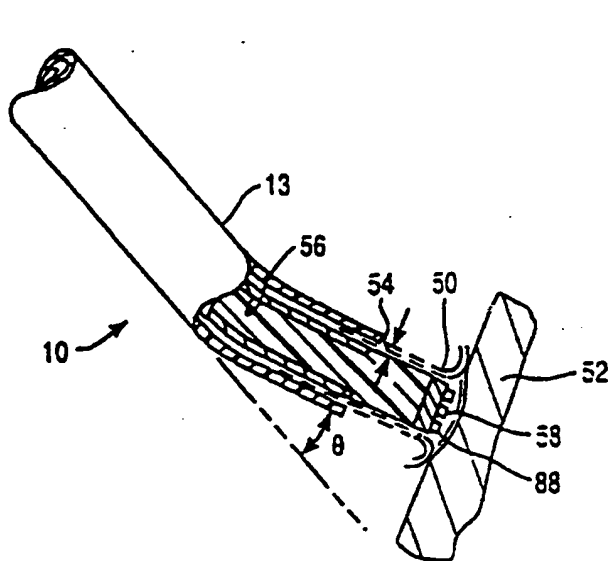


FIG. 10

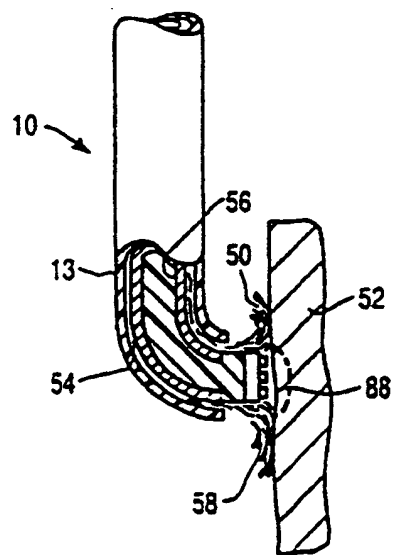


FIG. 11

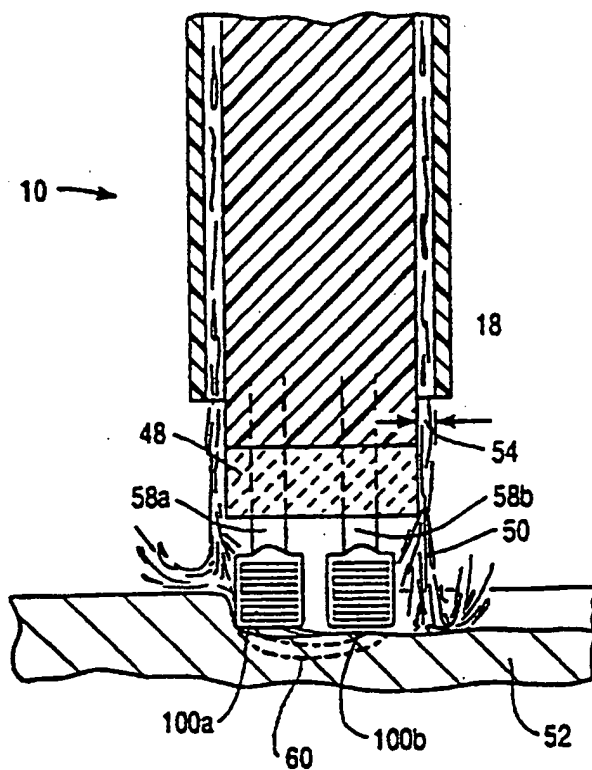


FIG. 12

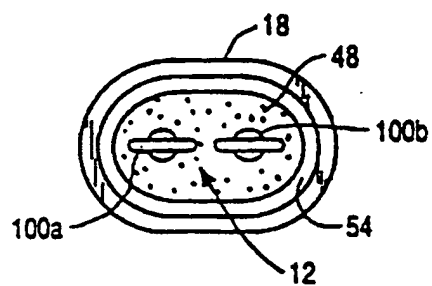


FIG. 13

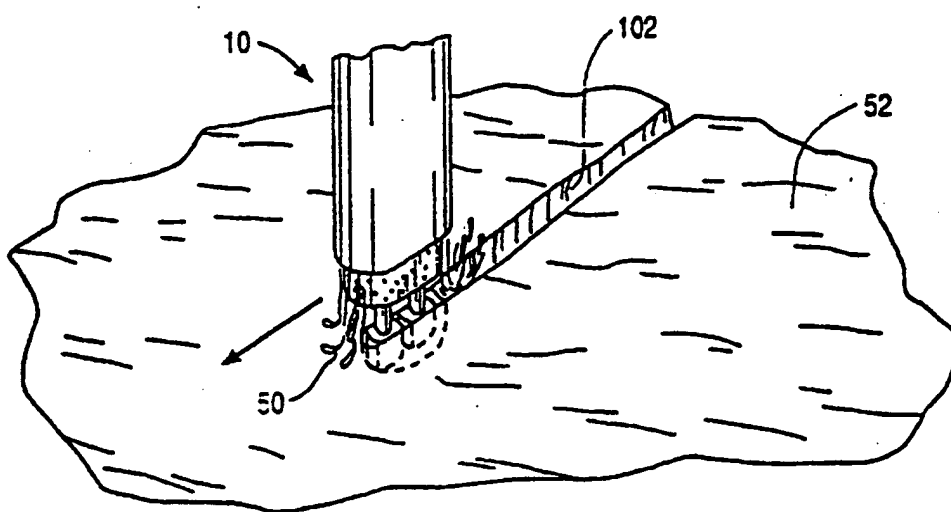


FIG. 14

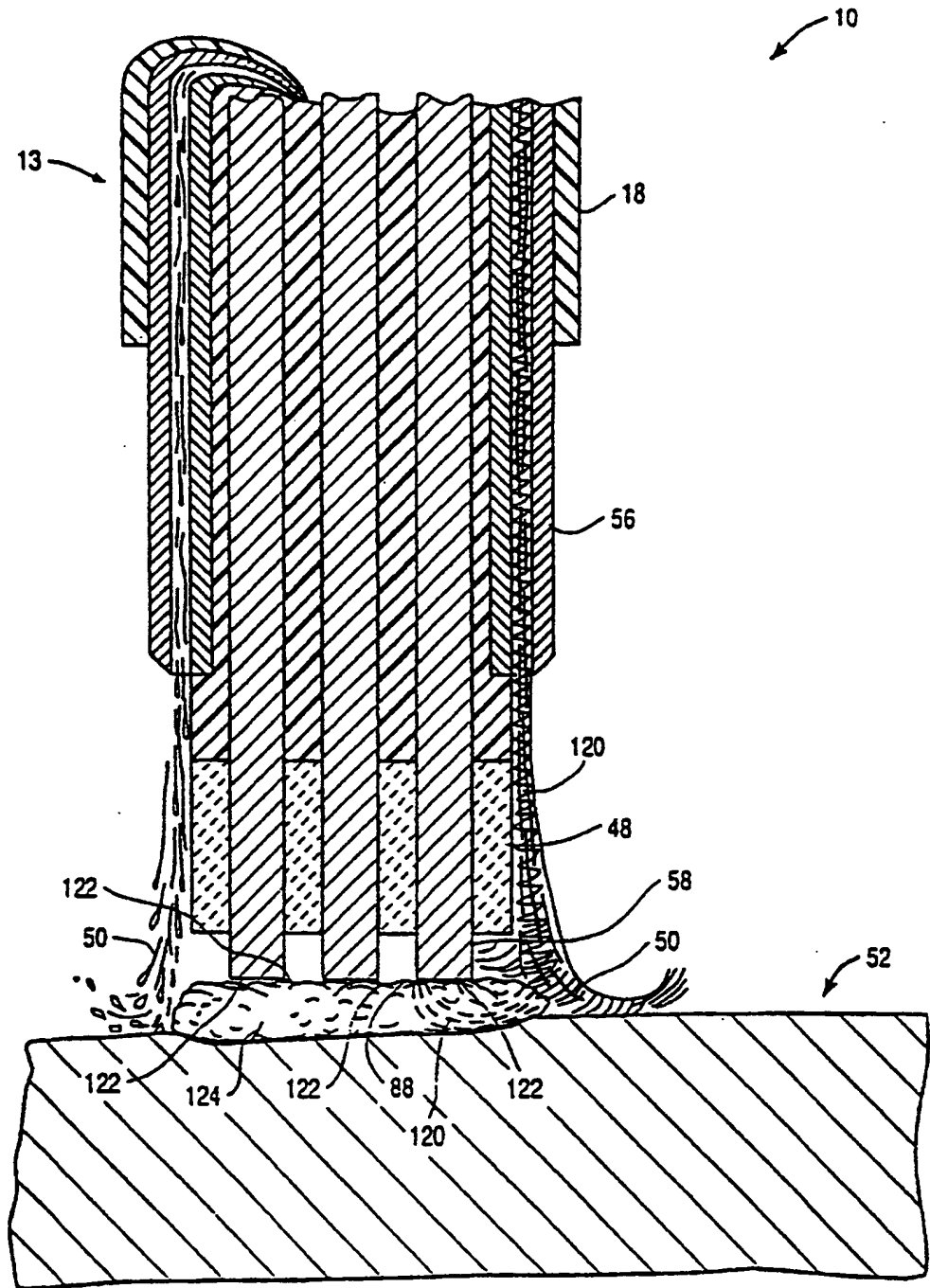


FIG. 15

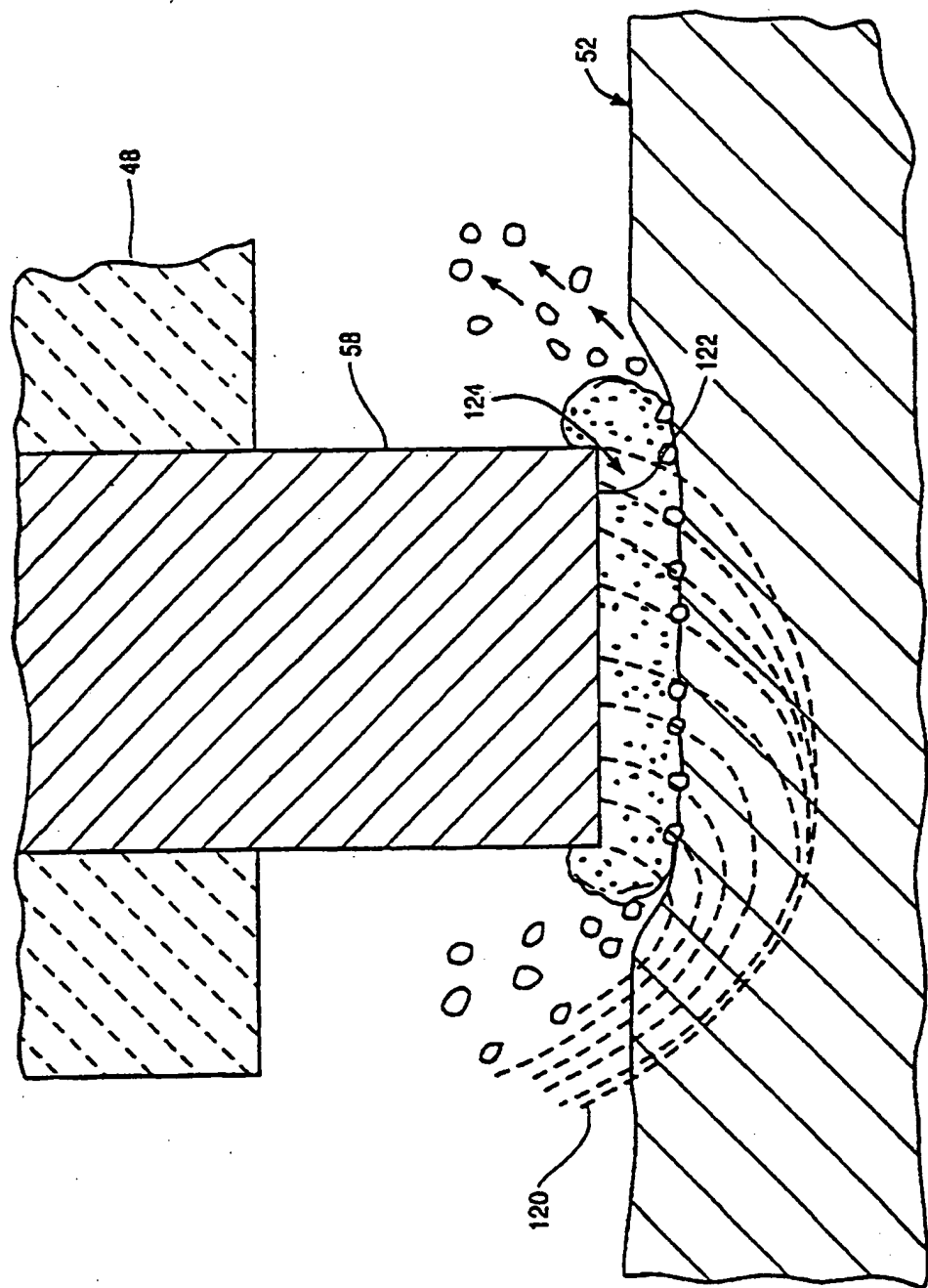


FIG. 16

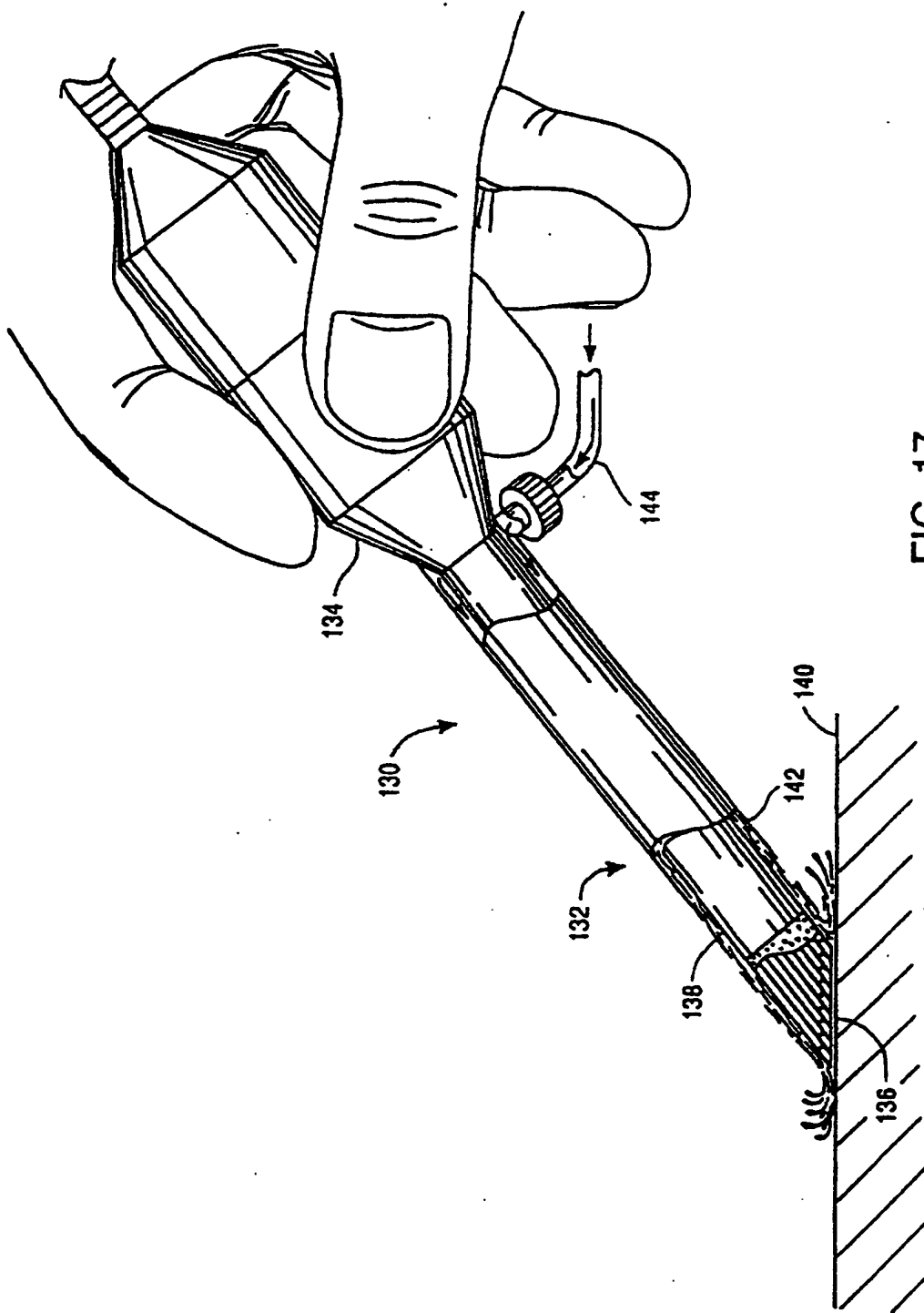


FIG. 17

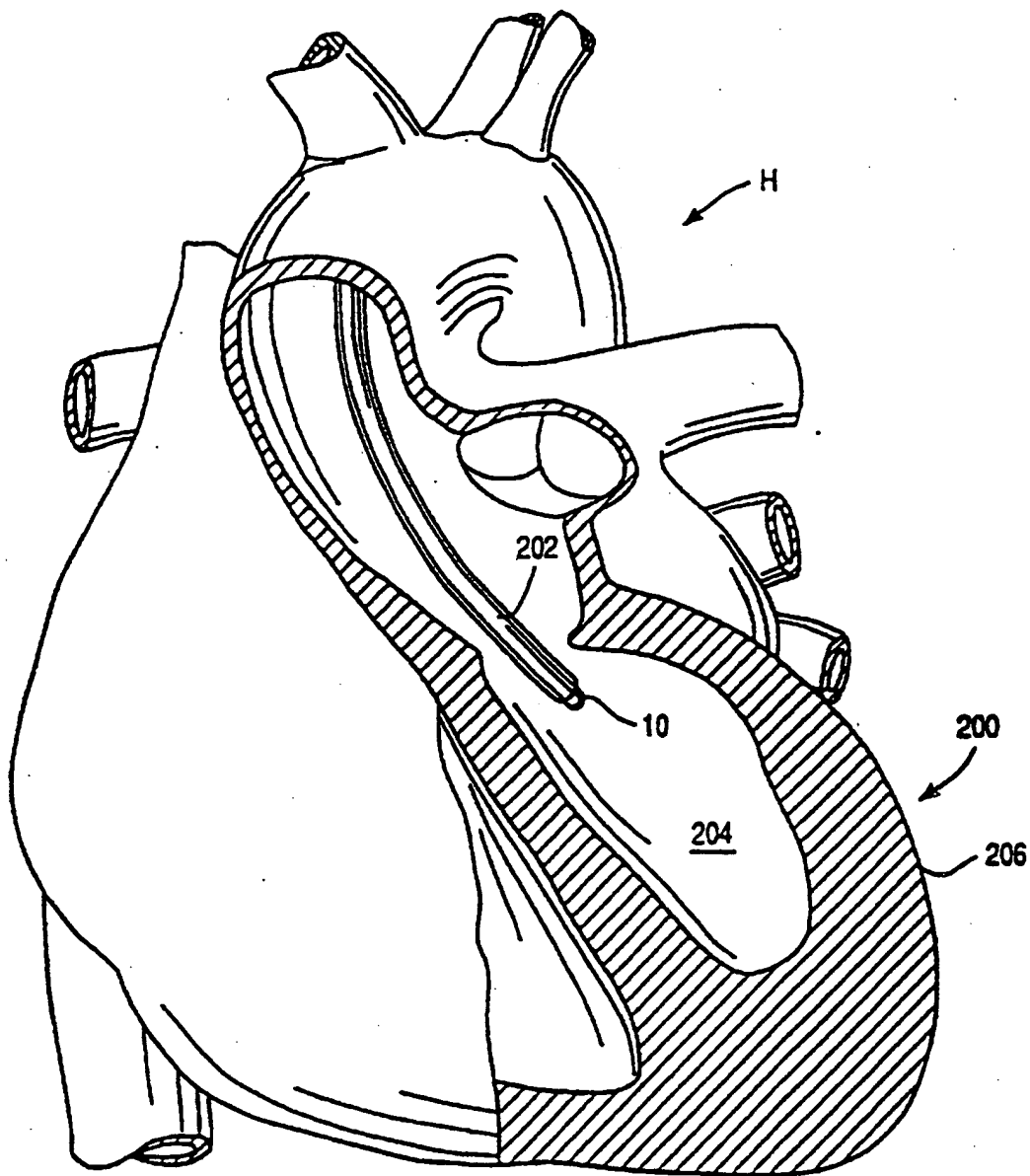


FIG. 18

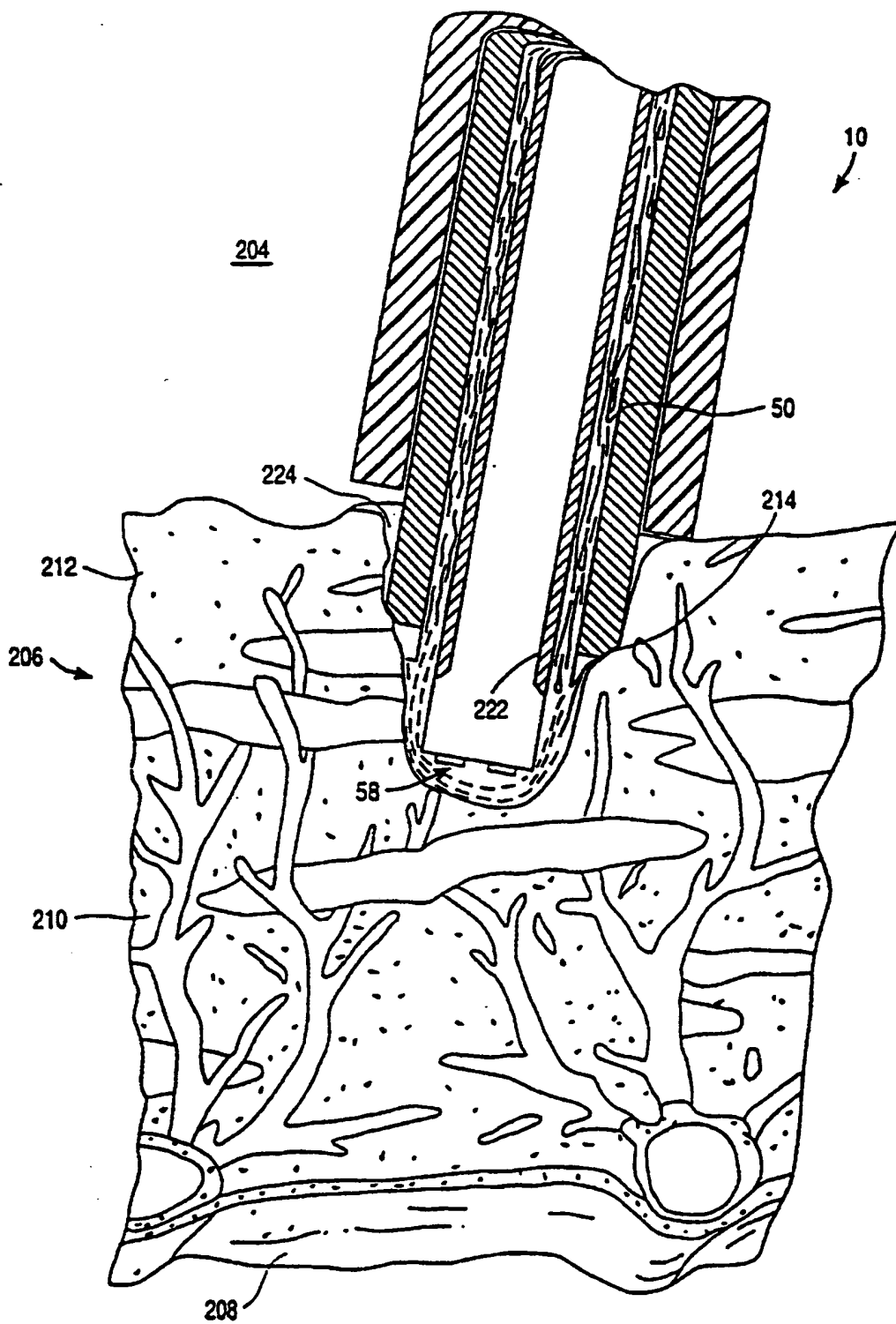


FIG. 19

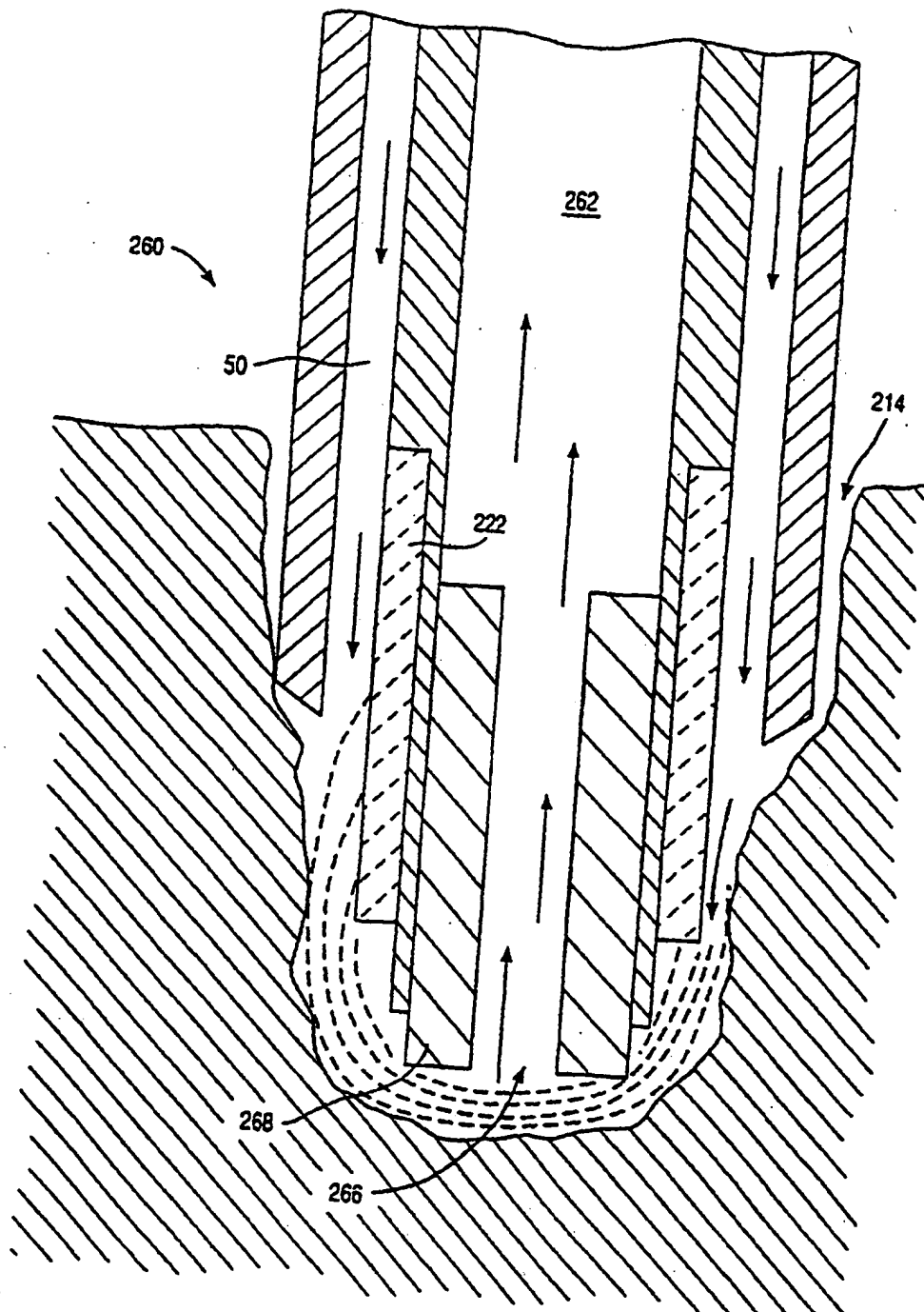


FIG. 20

A 450

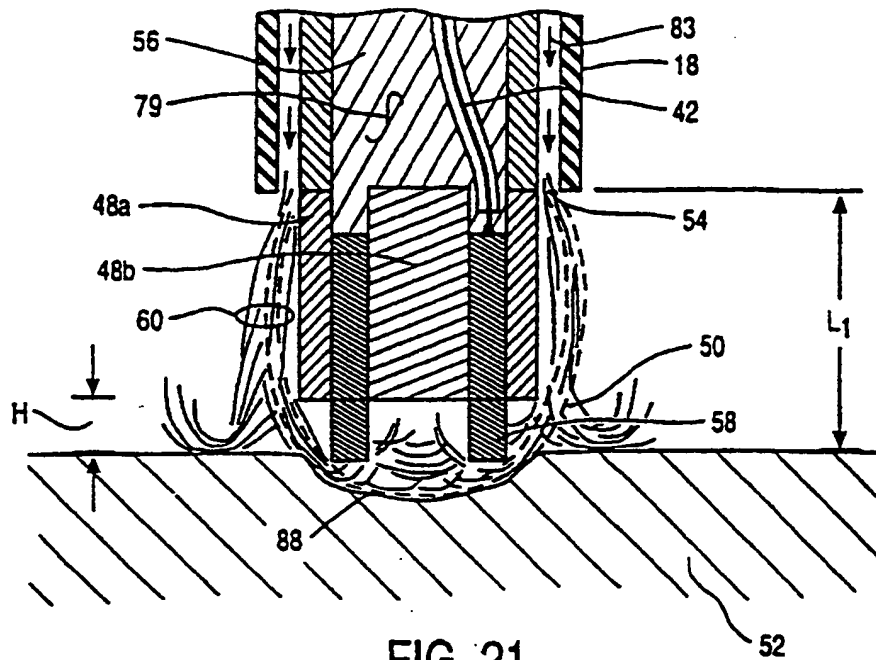


FIG. 21

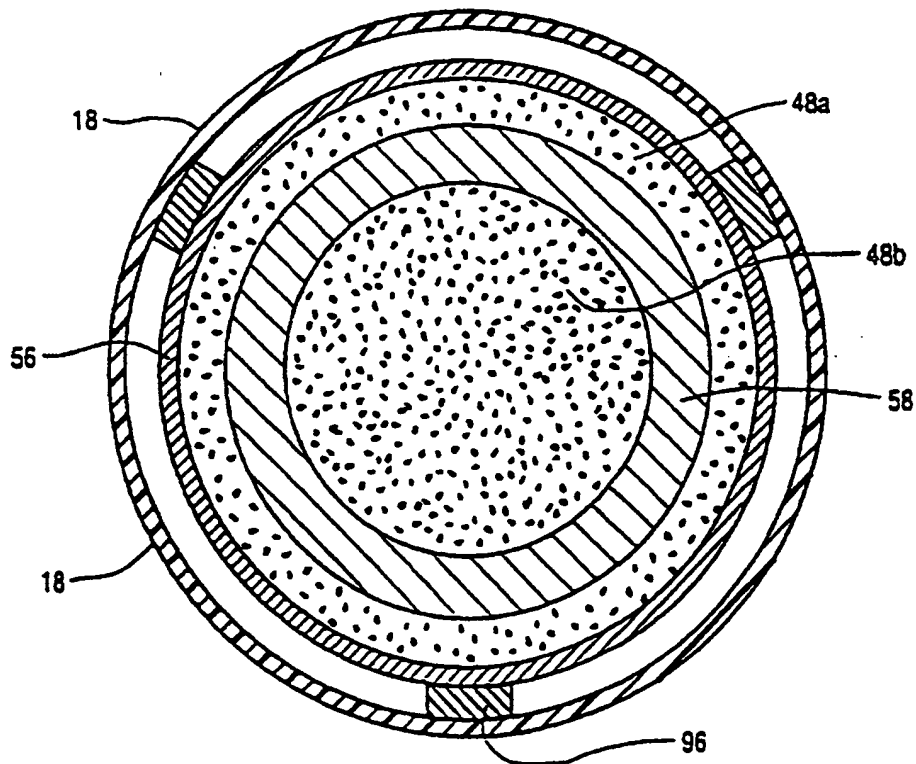


FIG. 22

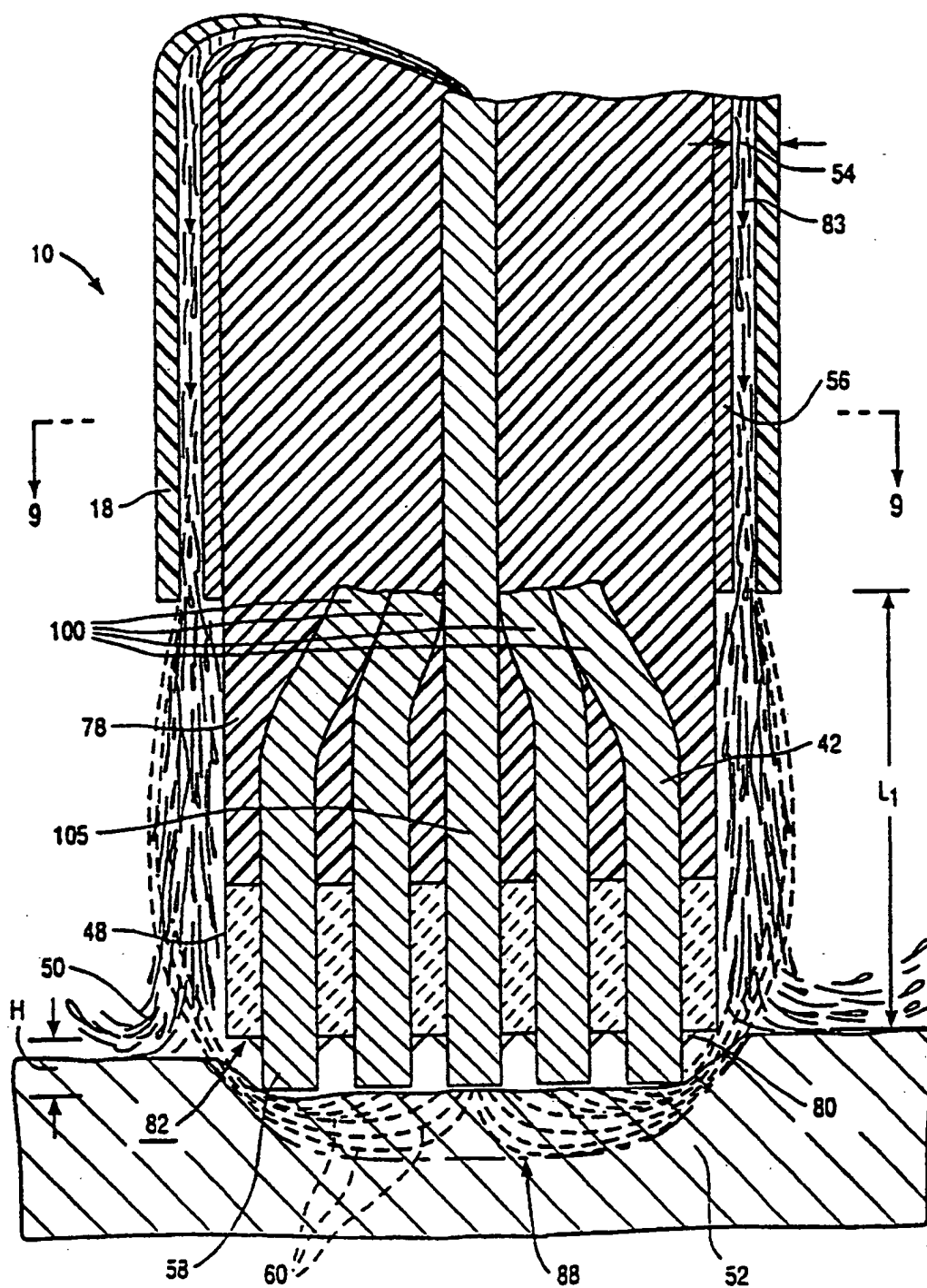


FIG. 23

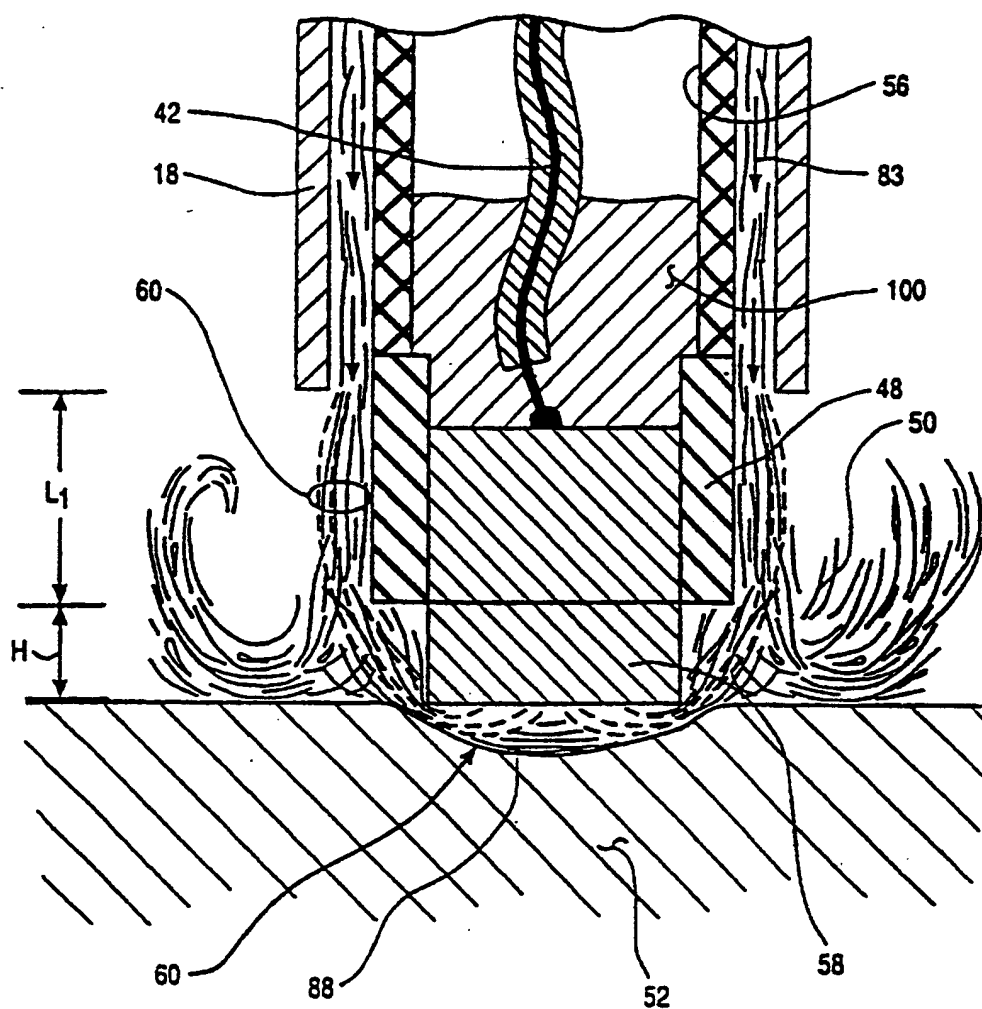


FIG. 24

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SYSTEMS AND METHODS FOR ELECTROSURGICAL TISSUE TREATMENT IN CONDUCTIVE FLUID

The present invention is a division of application Ser. No. 08/795,686, filed Feb. 5, 1997, now U.S. Pat. No. 5,871,469, which is a division of application Ser. No. 08/561,958, filed Nov. 22, 1995, now U.S. Pat. No. 5,697,882, which is a continuation-in-part of application Ser. No. 08/485,219, filed Jun. 7, 1995, now U.S. Pat. No. 5,697,281, which is a continuation-in-part of application Ser. No. 08/446,767 filed Jun. 2, 1995, now U.S. Pat. No. 5,697,909 which is a U.S. National Phase Filing of International Application No. PCT/US94/05168, filed May 10, 1994, which is a continuation-in-part of application Ser. No. 08/059,681, filed May 10, 1993, now abandoned, which is a continuation-in-part of application Ser. No. 07/958,977, filed Oct. 9, 1992, now U.S. Pat. No. 5,366,443, which is a continuation-in-part of application Ser. No. 07/817,575, filed Jan. 7, 1992, now abandoned, the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to the field of electrosurgery and, more particularly, to surgical devices and methods which employ high frequency voltage to cut and ablate tissue.

The field of electrosurgery includes a number of loosely related surgical techniques which have in common the application of electrical energy to modify the structure or integrity of patient tissue. Electrosurgical procedures usually operate through the application of very high frequency currents to cut or ablate tissue structures, where the operation can be monopolar or bipolar. Monopolar techniques rely on external grounding of the patient, where the surgical device defines only a single electrode pole. Bipolar devices comprise both electrodes for the application of current between their surfaces.

Electrosurgical procedures and techniques are particularly advantageous since they generally reduce patient bleeding and trauma associated with cutting operations. Current electrosurgical device and procedures, however, suffer from a number of disadvantages. For example, monopolar devices generally direct electric current along a defined path from the exposed or active electrode through the patient's body to the return electrode, which is externally attached to a suitable location on the patient. This creates the potential danger that the electric current will flow through undefined paths in the patient's body, thereby increasing the risk of unwanted electrical stimulation to portions of the patient's body. In addition, since the defined path through the patient's body has a relatively high impedance (because of the large distance or resistivity of the patient's body), large voltage differences must typically be applied between the return and active electrodes in order to generate a current suitable for ablation or cutting of the target tissue. This current, however, may inadvertently flow along body paths having less impedance than the defined electrical path, which will substantially increase the current flowing through these paths, possibly causing damage to or destroying tissue along and surrounding this pathway.

Bipolar electrosurgical devices have an inherent advantage over monopolar devices because the return current path does not flow through the patient. In bipolar electrosurgical devices, both the active and return electrode are typically

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exposed so that they may both contact tissue, thereby providing a return current path from the active to the return electrode through the tissue. One drawback with this configuration, however, is that the return electrode may cause tissue desiccation or destruction at its contact point with the patient's tissue. In addition, the active and return electrodes are typically positioned close together to ensure that the return current flows directly from the active to the return electrode. The close proximity of these electrodes generates the danger that the current will short across the electrodes, possibly impairing the electrical control system and/or damaging or destroying surrounding tissue.

The use of electrosurgical procedures (both monopolar and bipolar) in electrically conductive environments can be further problematic. For example, many arthroscopic procedures require flushing of the region to be treated with isotonic saline (also referred to as normal saline), both to maintain an isotonic environment and to keep the field of viewing clear. The presence of saline, which is a highly conductive electrolyte, can also cause shorting of the electrosurgical electrode in both monopolar and bipolar modes. Such shorting causes unnecessary heating in the treatment environment and can further cause non-specific tissue destruction.

Many surgical procedures, such as oral, laparoscopic and open surgical procedures, are not performed with the target tissue submerged under an irrigant. In laparoscopic procedures, such as the resection of the gall bladder from the liver, for example, the abdominal cavity is pressurized with carbon dioxide (pneumoperitoneum) to provide working space for the instruments and to improve the surgeon's visibility of the surgical site. Other procedures, such as the ablation of muscle or gingiva tissue in the mouth, the ablation and necrosis of diseased tissue, or the ablation of epidermal tissue, are also typically performed in a "dry" environment or field (i.e., not submerged under an electrically conducting irrigant).

Present electrosurgical techniques used for tissue ablation also suffer from an inability to control the depth of necrosis in the tissue being treated. Most electrosurgical devices rely on creation of an electric arc between the treating electrode and the tissue being cut or ablated to cause the desired localized heating. Such arcs, however, often create very high temperatures causing a depth of necrosis greater than 500 μm , frequently greater than 800 μm , and sometimes as great as 1700 μm . The inability to control such depth of necrosis is a significant disadvantage in using electrosurgical techniques for tissue ablation, particularly in arthroscopic procedures for abating and/or reshaping fibrocartilage, articular cartilage, meniscal tissue, and the like.

In an effort to overcome at least some of these limitations of electrosurgery, laser apparatus have been developed for use in arthroscopic and other procedures. Lasers do not suffer from electrical shorting in conductive environments, and certain types of lasers allow for very controlled cutting with limited depth of necrosis. Despite these advantages, laser devices suffer from their own set of deficiencies. In the first place, laser equipment can be very expensive because of the costs associated with the laser light sources. Moreover, those lasers which permit acceptable depths of necrosis (such as eximer lasers, erbium:YAG lasers, and the like) provide a very low volumetric ablation rate, which is a particular disadvantage in cutting and ablation of fibrocartilage, articular cartilage, and meniscal tissue. The holmium:YAG and Nd:YAG lasers provide much higher volumetric ablation rates, but are much less able to control depth of necrosis than are the slower laser devices. The CO_2

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lasers provide high rate of ablation and low depth of tissue necrosis, but cannot operate in a liquid-filled cavity.

For these and other reasons, improved systems and methods are desired for the electrosurgical ablation and cutting of tissue. These systems and methods should be capable of selectively cutting and ablating tissue and other body structures in electrically conductive environments, such as regions filled with blood or irrigated with electrically conductive solutions, such as isotonic saline, and in relatively dry environments, such as those encountered in oral, dermatological, laparoscopic, thoracoscopic and open surgical procedures. Such apparatus and methods should be able to perform cutting and ablation of tissues, while limiting the depth of necrosis and limiting the damage to tissue adjacent to the treatment site.

2. Description of the Background Art

Devices incorporating radio frequency electrodes for use in electrosurgical and electrocautery techniques are described in Rand et al. (1985) *J. Arthro. Surg.* 1:242-246 and U.S. Pat. Nos. 5,281,216; 4,943,290; 4,936,301; 4,593,691; 4,228,800; and 4,202,337. U.S. Pat. Nos. 4,943,290 and 4,036,301 describe methods for injecting non-conducting liquid over the tip of a monopolar electrosurgical electrode to electrically isolate the electrode, while energized, from a surrounding electrically conducting irrigant. U.S. Pat. Nos. 5,195,959 and 4,674,499 describe monopolar and bipolar electrosurgical devices, respectively, that include a conduit for irrigating the surgical site.

U.S. Pat. Nos. 5,217,455, 5,423,803, 5,102,410, 5,282,797, 5,290,273, 5,304,170, 5,312,395, 5,336,217 describe laser treatment methods for removing abnormal skin cells, such as pigmentations, lesions, soft tissue and the like. U.S. Pat. Nos. 5,445,634 and 5,370,642 describe methods for using laser energy to divide, incise or resect tissue during cosmetic surgery. U.S. Pat. No. 5,261,410 is directed to a method and apparatus for detecting and removing malignant tumor tissue. U.S. Pat. Nos. 5,380,316, 4,658,817, 5,389,096, PCT application No. WO 94/14383 and European Patent Application No. 0 515 867 describe methods and apparatus for percutaneous myocardial revascularization. These methods and apparatus involve directing laser energy against the heart tissue to form transverse channels through the myocardium to increase blood flow from the ventricular cavity to the myocardium.

SUMMARY OF THE INVENTION

The present invention provides a system and method for selectively applying electrical energy to structures within or on the surface of a patient's body. The system and method allow the surgical team to perform electrosurgical interventions, such as ablation and cutting of body structures, while limiting the depth of necrosis and limiting damage to tissue adjacent the treatment site. The system and method of the present invention are useful for surgical procedures in relatively dry environments, such as treating and shaping gingiva, for tissue dissection, e.g. separation of gall bladder from the liver, ablation and necrosis of diseased tissue, such as fibroid tumors, and dermatological procedures involving surface tissue ablation on the epidermis, such as scar or tattoo removal, tissue rejuvenation and the like. The present invention may also be useful in electrically conducting environments, such as arthroscopic or cystoscopic surgical procedures. In addition, the present invention is useful for canalizing or boring channels or holes through tissue, such as the ventricular wall of the heart during transmyocardial revascularization procedures.

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The method of the present invention comprises positioning an electrosurgical probe adjacent the target tissue so that at least one active electrode is brought into close proximity to the target site. A return electrode is positioned within an electrically conducting liquid, such as isotonic saline, to generate a current flow path between the target site and the return electrode. High frequency voltage is then applied between the active and return electrode through the current flow path created by the electrically conducting liquid in either a bipolar or monopolar manner. The probe may then be translated, reciprocated or otherwise manipulated to cut the tissue or effect the desired depth of ablation.

The current flow path may be generated by submerging the tissue site in an electrical conducting fluid (e.g., arthroscopic surgery and the like) or by directing an electrically conducting liquid along a fluid path past the return electrode and to the target site to generate the current flow path between the target site and the return electrode. This latter method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid), such as open, endoscopic or oral surgery, because the electrically conducting liquid provides a suitable current flow path from the target site to the return electrode. The active electrode is preferably disposed at the distal end of the probe and the return electrode is spaced from the active electrode and enclosed within an insulating sheath. This minimizes exposure of the return electrode to surrounding tissue and minimizes possible shorting of the current between the active and return electrodes. In oral procedures, the probe may be introduced directly into the cavity of the open mouth so that the active electrode is positioned against gingival or mucosal tissue. In endoscopic procedures, the probe will typically be passed through a conventional trocar cannula while viewing of the operative site is provided through the use of a laparoscope disposed in a separate cannula.

In a specific aspect of the invention, the high frequency voltage applied between the active and return electrodes generates high voltage gradients in the vicinity of the probe tip. These high voltage gradients are sufficient to create an electric field at the distal boundary of the active electrode(s) that is sufficiently high to break down the tissue through molecular dissociation or disintegration. The high frequency voltage imparts energy to the target site to ablate a thin layer of tissue without causing substantial tissue necrosis beyond the boundary of the thin layer of tissue ablated. This ablative process can be precisely controlled to effect the volumetric removal of tissue as thin as a few layers of cells with minimal heating of or damage to surrounding or underlying tissue structures.

Applicants believe that this precisely controlled ablation is at least partly caused by the high electric field generated around the tip of the active electrode(s) within the electrically conductive liquid. The electric field vaporizes the electrically conductive liquid into a thin layer over at least a portion of the active electrode surface and then ionizes the vapor layer due to the presence of an ionizable species within the liquid. This ionization and the presence of high electric fields in a low density vaporized layer induces the discharge of highly energetic electrons and photons in the form of ultraviolet energy from the vapor layer. The ultraviolet energy and/or energetic electrons cause disintegration of the tissue molecules adjacent to the vapor layer. This energy discharge can be precisely controlled to effect the volumetric removal of tissue thicknesses ranging from millimeters to a few layers of cells without heating or otherwise damaging surrounding or underlying cell structures.

The active electrode(s) will be spaced away from the target tissue by a suitable distance during the ablation

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process. This spacing allows for the continual resupply of electrically conducting liquid at the interface between the active electrode(s) and the target tissue surface. This continual resupply of the electrically conducting liquid helps to ensure that the thin vapor layer or region will remain over at least a portion of the active electrode(s) between the active electrode(s) and the tissue surface. Preferably, the active electrode(s) will be translated and/or rotated transversely relative to the tissue, i.e., in a light brushing motion, to maintain the supply of electrically conducting fluid in the region between the active electrode(s) and the tissue. This dynamic movement of the active electrode(s) over the tissue site also allows the electrically conducting liquid to cool the tissue surrounding recently ablated areas to minimize damage to this surrounding tissue.

The apparatus according to the present invention comprises an electrosurgical probe having a shaft with a proximal end, a distal end, and at least one active electrode at or near the distal end. A connector is provided at or near the proximal end of the shaft for electrically coupling the active electrode to a high frequency voltage source. A return electrode coupled to the voltage source is spaced a sufficient distance from the active electrode to substantially avoid or minimize current shorting therebetween and, in dry environments, to shield the return electrode from tissue at the target site of ablation or from the surgeon. In irrigant flooded environments, such as arthroscopic surgery, the area of the return electrode is sufficiently large to result in low current densities that effectively preclude damage to nearby tissue. The return electrode may be provided integral with the shaft of the probe or it may be separate from the shaft (e.g., on a liquid supply instrument). In both cases, the return electrode defines an inner, annular surface of the pathway for flow of electrically conducting liquid therethrough. The liquid is directed past the surface of the return electrode and over the active electrode to thereby provide a return current flow path between the target tissue site and the return electrode.

The active and return electrodes will preferably be configured such that, upon the application of a sufficient high-frequency voltage, a thin layer of the electrically conducting liquid is vaporized over at least a portion of the active electrode(s) in the region between the active electrode(s) and the target tissue. To accomplish this, the active electrode(s) will be configured such that high electric field densities form at the distal tips of the active electrode(s). By way of example, the present invention may utilize an electrode array of electrode terminals flush with or recessed from or extending from the distal end of the probe. The electrode terminals will preferably have a sufficiently small area, extension (or recession) length from the probe and sharp edges and/or surface asperities such that localized high current densities are promoted on the electrode terminals which, in turn, lead to the formation of a vaporized layer or region over at least a portion of the active electrode(s) followed by the high electric field induced breakdown (i.e., ionization) of ionizable species within the vapor layer or region and the emission of photon and/or electrons of sufficient energy to cause dissociation of molecules within the target tissue.

In an exemplary embodiment, the active electrode(s) are sized and arranged to create localized sources of energy (e.g., point sources or sources with a relatively small effective radius) at the distal tips of the electrode(s) when a sufficiently high frequency voltage is applied to the return and active electrodes. These small localized sources generate intense energy at the distal ends of the electrodes for molecular dissociation or ablation of tissue in contact with

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or in close proximity to the electrode tips. In addition, since the localized sources have relatively small radii, the energy flux decreases with the square of the distance from the localized sources so that the tissue at greater distances from the electrode tips are not significantly affected by the energy flux.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the electrosurgical system including an electrosurgical probe, an electrically conducting liquid supply and an electrosurgical power supply constructed in accordance with the principles of the present invention;

FIG. 2A is an enlarged, cross-sectional view of the distal tip of the electrosurgical probe of FIG. 1 illustrating an electrode arrangement suitable for rapid cutting and ablation of tissue structures;

FIG. 2B is an enlarged end view of the distal tip of the electrosurgical probe of FIG. 1;

FIG. 2C is a cross-sectional view of the proximal end of the electrosurgical probe, illustrating an arrangement for coupling the probe to the electrically conducting liquid supply of FIG. 1;

FIG. 3 is a detailed cross-sectional view of an alternative embodiment of the electrosurgical probe of FIG. 1;

FIG. 4 is an end view of the distal end of the electrosurgical probe of FIG. 3;

FIG. 5 is an end view of another embodiment of the electrosurgical probe of FIG. 1;

FIG. 6 is a partial cross-sectional side view of a further embodiment of the electrosurgical probe with the electrode array disposed transversely to the axis of the probe;

FIG. 7 is a partial front cross-sectional view of an electrosurgical probe and an electrically conductive liquid supply shaft illustrating use of the probe and the shaft in ablating target tissue;

FIG. 8 is an enlarged, cross-sectional view of the distal tip of yet another embodiment of the electrosurgical probe of FIG. 1;

FIG. 9 is a detailed end view of the probe of FIG. 8;

FIG. 10 is a side view of an electrosurgical probe having a shaft with an angled distal portion;

FIG. 11 is a side view of an electrosurgical probe having a shaft with a perpendicular distal portion;

FIG. 12 is a schematic view of an electrosurgical probe having two screwdriver-shaped electrodes extending from the distal end;

FIG. 13 is an end view of the probe of FIG. 12;

FIG. 14 illustrates use of the probe of FIG. 12 for the rapid cutting of tissue;

FIG. 15 is a cross-sectional view of the distal tip of the electrosurgical probe, illustrating electric field lines between the active and return electrodes;

FIG. 16 is an enlarged cross-sectional view of the distal tip of the probe of FIG. 15, illustrating a vapor layer formed between the active electrodes and the target tissue;

FIG. 17 is a cross-sectional view of an alternative electrosurgical probe for applying high frequency voltage to epidermal tissue layers;

FIG. 18 is a sectional view of the human heart, illustrating the electrosurgical probe within the ventricular cavity for performing a transmyocardial revascularization procedure;

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FIG. 19 is a cross-sectional view of the probe boring a channel through the ventricular wall;

FIG. 20 depicts an alternative embodiment of the probe of FIG. 19 having an inner lumen for aspirating fluid and gases from the transmural channel;

FIG. 21 depicts a distal portion of an alternative embodiment of the probe of FIGS. 2A-2C incorporating a single electrode with a tubular geometry;

FIG. 22 is a cross-sectional view of the distal end of the probe of FIG. 21;

FIG. 23 is a side cross-sectional view of a distal portion of a further embodiment of the probe of FIGS. 2A-2C incorporating a multiplicity of electrodes which converge to a single electrode lead; and

FIG. 24 is a side cross-sectional view of a distal portion of yet another embodiment of the probe of FIGS. 2A-2C incorporating a single electrode connected to a single electrode lead.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention provides a system and method for selectively applying electrical energy to a target location within or on a patient's body, such as solid tissue or the like, particularly including gingival tissues and mucosal tissues located in the mouth or epidermal tissue on the outer skin. In addition, tissues which may be treated by the system and method of the present invention include tumors, abnormal tissues, and the like. The invention may also be used for canalizing or boring channels or holes through tissue, such as the ventricular wall during transmural revascularization procedures. For convenience, the remaining disclosure will be directed specifically to the cutting, shaping or ablation of gingival or mucosal tissue in oral surgical procedures, the surface tissue ablation of the epidermis in dermatological procedures and the canalization of channels through the myocardium of the heart, but it will be appreciated that the system and method can be applied equally well to procedures involving other tissues of the body, as well as to other procedures including open surgery, laparoscopic surgery, thoracoscopic surgery, and other endoscopic surgical procedures.

In addition, the present invention is particularly useful in procedures where the tissue site is flooded or submerged with an electrically conducting fluid, such as isotonic saline. Such procedures, e.g., arthroscopic surgery and the like, are described in detail in co-pending PCT International Application, U.S. National Phase Ser. No. PCT/US94/05168, filed on May 10, 1994, the complete disclosure of which has been incorporated herein by reference.

The present invention may use a single active electrode or an electrode array distributed over a distal contact surface of a probe. The electrode array usually includes a plurality of independently current-limited and/or power-controlled electrode terminals to apply electrical energy selectively to the target tissue while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power dissipation into surrounding electrically conductive liquids, such as blood, normal saline, and the like. The electrode terminals may be independently current-limited by using isolating the terminals from each other and connecting each terminal to a separate power source that is isolated from the other electrode terminals. Alternatively, the electrode terminals may be connected to each other at either the proximal or distal ends of the probe to form a single wire that couples to a power source.

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The electrosurgical probe will comprise a shaft having a proximal end and a distal end which supports an active electrode. The shaft may assume a wide variety of configurations, with the primary purpose being to mechanically support the active electrode and permit the treating physician to manipulate the electrode from a proximal end of the shaft. Usually, the shaft will be a narrow-diameter rod or tube, more usually having dimensions which permit it to be introduced into a body cavity, such as the mouth or the abdominal cavity, through an associated trocar or cannula in a minimally invasive procedure, such as arthroscopic, laparoscopic, thoracoscopic, and other endoscopic procedures. Thus, the shaft will typically have a length of at least 5 cm for oral procedures and at least 10 cm, more typically being 20 cm, or longer for endoscopic procedures. The shaft will typically have a diameter of at least 1 mm and frequently in the range from 1 to 10 mm. Of course, for dermatological procedures on the outer skin, the shaft may have any suitable length and diameter that would facilitate handling by the surgeon.

The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft. Specific shaft designs will be described in detail in connection with the figures hereinafter.

The circumscribed area of the electrode array is in the range from 0.25 mm² to 75 mm², preferably from 0.5 mm² to 40 mm², and will usually include at least two isolated electrode terminals, more usually at least four electrode terminals, preferably at least six electrode terminals, and often 50 or more electrode terminals, disposed over the distal contact surfaces on the shaft. By bringing the electrode array(s) on the contact surface(s) in close proximity with the target tissue and applying high frequency voltage between the array(s) and an additional common or return electrode in direct or indirect contact with the patient's body, the target tissue is selectively ablated or cut, permitting selective removal of portions of the target tissue while desirably minimizing the depth of necrosis to surrounding tissue. In particular, this invention provides a method and apparatus for effectively ablating and cutting tissue which may be located in close proximity to other critical organs, vessels or structures (e.g., teeth, bone) by simultaneously (1) causing electrically conducting liquid to flow between the common and active electrodes, (2) applying electrical energy to the target tissue surrounding and immediately adjacent to the tip of the probe, (3) bringing the active electrode(s) in close proximity with the target tissue using the probe itself, and (4) optionally moving the electrode array axially and/or transversely over the tissue.

In one configuration, each individual electrode terminal in the electrode array is electrically insulated from all other electrode terminals in the array within said probe and is connected to a power source which is isolated from each of the other electrodes in the array or to circuitry which limits or interrupts current flow to the electrode when low resistivity material (e.g., blood or electrically conductive saline irrigant) causes a lower impedance path between the common electrode and the individual electrode terminal. The isolated power sources for each individual electrode may be separate power supply circuits having internal impedance

characteristics which limit power to the associated electrode terminal when a low impedance return path is encountered, may be a single power source which is connected to each of the electrodes through independently actuatable switches or may be provided by independent current limiting elements, such as inductors, capacitors, resistors and/or combinations thereof. The current limiting elements may be provided in the probe, connectors, cable, controller or along the conductive path from the controller to the distal tip. Alternatively, the resistance and/or capacitance may occur on the surface of the active electrode(s) due to oxide layers which form selected electrode terminals (e.g., titanium or a resistive coating on the surface of metal, such as platinum)

The tip region of the probe may be composed of many independent electrode terminals designed to deliver electrical energy in the vicinity of the tip. The selective application of electrical energy to the target tissue is achieved by connecting each individual electrode terminal and the common electrode to a power source having independently controlled or current limited channels. The common electrode may be a tubular member of conductive material proximal to the electrode array at the tip which also serves as a conduit for the supply of the electrically conducting liquid between the active and common electrodes. The application of high frequency voltage between the common electrode and the electrode array results in the generation of high electric field intensities at the distal tips of the electrodes with conduction of high frequency current from each individual electrode terminal to the common electrode. The current flow from each individual electrode terminal to the common electrode is controlled by either active or passive means, or a combination thereof, to deliver electrical energy to the target tissue while minimizing energy delivery to surrounding (non-target) tissue and any conductive fluids which may be present (e.g., blood, electrolytic irrigants such as saline, and the like).

In a preferred aspect, this invention takes advantage of the differences in electrical resistivity between the target tissue (e.g., gingiva, muscle, fascia, tumor, epidermal, heart or other tissue) and the surrounding conductive liquid (e.g., isotonic saline irrigant). By way of example, for any selected level of applied voltage, if the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is isotonic saline irrigant liquid (having a relatively low electrical impedance), the current control means connected to the individual electrode will limit current flow so that the heating of intervening conductive liquid is minimized. On the other hand, if a portion of or all of the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is gingival tissue (having a relatively higher electrical impedance), the current control circuitry or switch connected to the individual electrode will allow current flow sufficient for the deposition of electrical energy and associated ablation or electrical breakdown of the target tissue in the immediate vicinity of the electrode surface.

The application of a high frequency voltage between the common or return electrode and the electrode array for appropriate time intervals effects ablation, cutting or reshaping of the target tissue. The tissue volume over which energy is dissipated (i.e., a high voltage gradient exists) may be precisely controlled, for example, by the use of a multiplicity of small electrodes whose effective diameters range from about 2 mm to 0.01 mm, preferably from about 1 mm to 0.05 mm, and more preferably from about 0.5 mm to 0.1 mm. Electrode areas for both circular and non-circular terminals

will have a contact area (per electrode) below 5 mm², preferably being in the range from 0.0001 mm² to 1 mm², and more preferably from 0.005 mm² to 0.5 mm². The use of small diameter electrode terminals increases the electric field intensity and reduces the extent or depth of tissue necrosis as a consequence of the divergence of current flux lines which emanate from the exposed surface of each electrode terminal. Energy deposition in tissue sufficient for irreversible damage (i.e., necrosis) has been found to be limited to a distance of about one-half to one electrode diameter. This is a particular advantage over prior electro-surgical probes employing single and/or larger electrodes where the depth of tissue necrosis may not be sufficiently limited.

In previous electrosurgical devices, increased power application and ablation rates have been achieved by increasing the electrode area. Surprisingly, with the present invention, it has been found that the total electrode area can be increased (to increase power delivery and ablation rate) without increasing the depth of necrosis by providing multiple small electrode terminals. Preferably, the terminals will be spaced apart by a distance in the range from about one-half diameter to one diameter for optimum power delivery, as discussed below. The depth of necrosis may be further controlled by switching the applied voltage off and on to produce pulses of current, the pulses being of sufficient duration and associated energy density to effect ablation and/or cutting while being turned off for periods sufficiently long to allow for thermal relaxation between energy pulses. In this manner, the energy pulse duration and magnitude and the time interval between energy pulses are selected to achieve efficient rates of tissue ablation or cutting while allowing the temperature of the treated zone of tissue to "relax" or return to normal physiologic temperatures (usually to within 10° C. of normal body temperature [37° C.], preferably to within 5° C.) before the onset of the next energy (current) pulse.

In addition to the above described methods, the applicant has discovered another mechanism for ablating tissue while minimizing the depth of necrosis. This mechanism involves applying a high frequency voltage between the active electrode surface and the return electrode to develop high electric field intensities in the vicinity of the target tissue site. The high electric field intensities lead to electric field induced molecular breakdown of target tissue through molecular dissociation (rather than thermal evaporation or carbonization). In other words, the tissue structure is volumetrically removed through molecular disintegration of complex organic molecules into non-viable hydrocarbons and nitrogen compounds. This molecular disintegration completely removes the tissue structure, as opposed to transforming the tissue material from a solid form directly to a vapor form, as is typically the case with ablation.

The high electric field intensities may be generated by applying a high frequency voltage that is sufficient to vaporize the electrically conducting liquid over at least a portion of the active electrode(s) in the region between the distal tip of the active electrode and the target tissue. Since the vapor layer or vaporized region has a relatively high electrical impedance, it increases the voltages differential between the active electrode tip and the tissue and causes ionization within the vapor layer due to the presence of an ionizable species (e.g., sodium when isotonic saline is the electrically conducting fluid). This ionization, under optimal conditions, induces the discharge of energetic electrons and photons from vapor layer and to the surface of the target tissue. This energy may be in the form of energetic photons

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(e.g., ultraviolet radiation), energetic particles (e.g., electrons) or a combination thereof.

The necessary conditions for forming a vapor layer near the active electrode tip(s), ionizing the atom or atoms within the vapor layer and inducing the discharge of energy from plasma within the vapor layer will depend on a variety of factors, such as: the number of electrode terminals; electrode size and spacing; electrode surface area; asperities and sharp edges on the electrode surfaces; electrode materials; applied voltage and power; current limiting means, such as inductors; electrical conductivity of the fluid in contact with the electrodes; density of the fluid; and other factors. Based on initial experiments, applicants believe that the ionization of atoms within the vapor layer produced in isotonic saline (containing sodium chloride) leads to the generation of energetic photons having wavelengths, by way of example, in the range of 306 to 315 nanometers (ultraviolet spectrum) and 588 to 590 nanometers (visible spectrum). In addition, the free electrons within the ionized vapor layer are accelerated in the high electric fields near the electrode tip(s). When the density of the vapor layer (or within a bubble formed in the electrically conducting liquid) becomes sufficiently low (i.e., less than approximately 10^{20} atoms/cm³ for aqueous solutions), the electron mean free path increases to enable subsequently injected electrons to cause impact ionization within these regions of low density (i.e., vapor layers or bubbles). Energy evolved by the energetic electrons (e.g., 4 to 5 eV) can subsequently bombard a molecule and break its bonds, dissociating a molecule into free radicals, which then combine into final gaseous or liquid species.

The photon energy produces photoablation through photochemical and/or photothermal processes to disintegrate tissue thicknesses as small as several cell layers of tissue at the target site. This photoablation is a "cold" ablation, which means that the photon energy transfers very little heat to tissue beyond the boundaries of the region of tissue ablated. The cold ablation provided by photon energy can be precisely controlled to only affect a thin layer of cells without heating or otherwise damaging surrounding or underlying cells. The depth of necrosis will be typically be about 0 to 400 microns and usually 10 to 200 microns. Applicants believe that the "fragments" of disintegrated tissue molecules carry away much of the energy which is deposited on the surface of the target tissue, thereby allowing molecular disintegration of tissue to occur while limiting the amount of heat transfer to the surrounding tissue.

In addition, other competing mechanisms may be contributing to the ablation of tissue. For example, tissue destruction or ablation may also be caused by dielectric breakdown of the tissue structural elements or cell membranes from the highly concentrated intense electric fields at the tip portions of the electrode(s). According to the teachings of the present invention, the active electrode(s) are sized and have exposed surfaces areas which, under proper conditions of applied voltage, cause the formation of a vaporized region or layer over at least a portion of the surface of the active electrode(s). This layer or region of vaporized electrically conducting liquid creates the conditions necessary for ionization within the vaporized region or layer and the generation of energetic electrons and photons. In addition, this layer or region of vaporized electrically conducting liquid provides a high electrical impedance between the electrode and the adjacent tissue so that only low levels of current flow across the vaporized layer or region into the tissue, thereby minimizing joule heating in, and associated necrosis of, the tissue.

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As discussed above, applicants have found that the density of the electrically conducting liquid at the distal tips of the active electrodes should be less than a critical value to form a suitable vapor layer. For aqueous solutions, such as water or isotonic saline, this upper density limit is approximately 10^{20} atoms/cm³, which corresponds to about 3×10^{-3} grams/cm³. Applicants also believe that once the density in the vapor layer reaches a critical value (e.g., approximately 10^{20} atoms/cm³ for aqueous solutions), electron avalanche occurs. The growth of this avalanche is retarded when the space charge generated fields are on the order of the external field. Spatial extent of this region should be larger than the distance required for an electron avalanche to become critical and for an ionization front to develop. This ionization front develops and propagates across the vapor layer via a sequence of processes occurring the region ahead of the front, viz, heat by electron injection, lowering of the local liquid density below the critical value and avalanche growth of the charged particle concentration.

Electrons accelerated in the electric field within the vapor layer will apparently become trapped after one or a few scatterings. These injected electrons serve to create or sustain a low density region with a large mean free path to enable subsequently injected electrons to cause impact ionization within these regions of low density. The energy evolved at each recombination is on the order of half of the energy band gap (i.e., 4 to 5 eV). It appears that this energy can be transferred to another electron to generate a highly energetic electron. This second, highly energetic electron may have sufficient energy to bombard a molecule to break its bonds, i.e., dissociate the molecule into free radicals.

The electrically conducting liquid should have a threshold conductivity in order to suitably ionize the vapor layer for the inducement of energetic electrons and photons. The electrical conductivity of the fluid (in units of milliSiemens per centimeter or mS/cm) will usually be greater than 0.2 mS/cm, preferably will be greater than 2 mS/cm and more preferably greater than 10 mS/cm. In an exemplary embodiment, the electrically conductive fluid is isotonic saline, which has a conductivity of about 17 mS/cm. The electrical conductivity of the channel trailing the ionization front should be sufficiently high to maintain the energy flow required to heat the liquid at the ionization front and maintain its density below the critical level. In addition, when the electrical conductivity of the liquid is sufficiently high, ionic pre-breakdown current levels (i.e., current levels prior to the initiation of ionization within the vapor layer) are sufficient to also promote the initial growth of bubbles within the electrically conducting liquid (i.e., regions whose density is less than the critical density).

Asperities on the surface of the active electrode(s) appear to promote localized high current densities which, in turn, promote bubble nucleation at the site of the asperities whose enclosed density (i.e., vapor density) is below the critical density to initiate ionization breakdown within the bubble. Hence, a specific configuration of the present invention creates regions of high current densities on the tips of the electrode(s) (i.e., the surface of the electrode(s) which are to engage and ablate or cut tissue). Regions of high current densities can be achieved via a variety of methods, such as producing sharp edges and corners on the distal tips of the electrodes or vapor blasting, chemically etching or mechanically abrading the distal end faces of the active electrodes to produce surface asperities thereon. Alternatively, the electrode terminals may be specifically designed to increase the edge/surface area ratio of the electrode terminals. For example, the electrode terminal(s) may be hollow tubes

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having a distal, circumferential edge surrounding an opening. The terminals may be formed in an array as described above or in a series of concentric terminals on the distal end of the probe. High current densities will be generated around the circumferential edges of the electrode terminals to promote nucleate bubble formation.

The voltage applied between the common electrode and the electrode array will be at high or radio frequency, typically between about 5 kHz and 20 MHz, usually being between about 30 kHz and 2.5 MHz, and preferably being between about 50 kHz and 400 kHz. The RMS (root mean square) voltage applied will usually be in the range from about 5 volts to 1000 volts, preferably being in the range from about 50 volts to 800 volts, and more preferably being in the range from about 100 volts to 400 volts. These frequencies and voltages will result in peak-to-peak voltages and current that are sufficient to vaporize the electrically conductive liquid and, in turn, create the conditions within the vaporized region which result in high electric fields and emission of energetic photons and/or electrons to ablate tissue. Typically, the peak-to-peak voltage will be in the range of 200 to 2000 volts and preferably in the range of 300 to 1400 volts and more preferably in the range of 700 to 900 volts.

As discussed above, the voltage is usually delivered in a series of voltage pulses with a sufficiently high frequency (e.g., on the order of 5 kHz to 20 MHz) such that the voltage is effectively applied continuously (as compared with e.g., lasers claiming small depths of necrosis, which are generally pulsed about 10 to 20 Hz). In addition, the pulsed laser duty cycle (i.e., cumulative time in any one-second interval that energy is applied) is on the order of about 50% for the present invention, as compared with lasers which typically have a duty cycle of about 0.0001%.

Applicants believe that the present invention is capable of obtaining high ablation rates with effectively continuous mode operation and high duty cycles because the source of energy emitted from the edges and tips of the small electrode terminals is effectively a point source or a source having a relatively small effective radius. As is well known in the art, the flux emitted from a point source and crossing a boundary in spherical space generally decreases as the square of distance from the source. Thus, the "energy source" of the present invention (i.e., the intense electric field, the energetic photons or the energetic electrons) is highly concentrated by virtue of the geometry of the emitting electrodes and the source of energy at the tips of the electrodes. As a result, only those regions or areas that are very close to the electrode tips or source will be exposed to high energy fluxes. Consequently, ablation will typically only occur in tissue layers effectively in contact or in very close proximity with the tips of the electrodes. The tissue at greater distances from the electrode tips are not significantly affected since the energy flux is too low at these distances to irreversibly affect or damage tissue.

Usually, the current level will be selectively limited or controlled and the voltage applied will be independently adjustable, frequently in response to the resistance of tissues and/or fluids in the pathway between an individual electrode and the common electrode. Also, the applied current level may be in response to a temperature control means which maintains the target tissue temperature with desired limits at the interface between the electrode arrays and the target tissue. The desired tissue temperature along a propagating surface just beyond the region of ablation will usually be in the range from about 40° C. to 100° C., and more usually from about 50° C. to 60° C. The tissue being ablated (and

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hence removed from the operation site) immediately adjacent the electrode array may reach even higher temperatures.

The preferred power source of the present invention delivers a high frequency current selectable to generate average power levels ranging from tens of milliwatts to tens of watts per electrode, depending on the target tissue being ablated, the rate of ablation desired or the maximum allowed temperature selected for the probe tip. The power source allows the user to select the current level according to the specific requirements of a particular oral surgery, dermatological procedure, open surgery or other endoscopic surgery procedure.

The power source may be current limited or otherwise controlled so that undesired heating of electrically conductive fluids or other low electrical resistance media does not occur. In a presently preferred embodiment of the present invention, current limiting inductors are placed in series with each independent electrode terminal, where the inductance of the inductor is in the range of 10 μ H to 50,000 μ H, depending on the electrical properties of the target tissue, the desired ablation rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in co-pending PCT application No. PCT/US94/05168, the complete disclosure of which is incorporated herein by reference. Additionally, current limiting resistors may be selected. Preferably, these resistors will have a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual electrode in contact with a low resistance medium (e.g., saline irrigant), the resistance of the current limiting resistor increases significantly, thereby minimizing the power delivery from said electrode into the low resistance medium (e.g., saline irrigant).

As an alternative to such passive circuit structures, regulated current flow to each electrode terminal may be provided by a multi-channel power supply. A substantially constant current level for each individual electrode terminal within a range which will limit power delivery through a low resistance path, e.g., isotonic saline irrigant, and would be selected by the user to achieve the desired rate of cutting or ablation. Such a multi-channel power supply thus provides a substantially constant current source with selectable current level in series with each electrode terminal, wherein all electrodes will operate at or below the same, user selectable maximum current level. Current flow to all electrode terminals could be periodically sensed and stopped if the temperature measured at the surface of the electrode array exceeds user selected limits. Particular control system designs for implementing this strategy are well within the skill of the art.

Yet another alternative involves the use of one or several power supplies which allow one or several electrodes to be simultaneously energized and which include active control means for limiting current levels below a preselected maximum level. In this arrangement, only one or several electrodes would be simultaneously energized for a brief period. Switching means would allow the next one or several electrodes to be energized for a brief period. By sequentially energizing one or several electrodes, the interaction between adjacent electrodes can be minimized (for the case of energizing several electrode positioned at the maximum possible spacing within the overall envelope of the electrode array) or eliminated (for the case of energizing only a single electrode at any one time). As before, a resistance measurement means may be employed for each electrode prior to the application of power wherein a (measured) low resistance (below some preselected level) will prevent that electrode

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from being energized during a given cycle. By way of example, the sequential powering and control scheme of the present invention would function in a manner similar to an automobile distributor. In this example, an electrical contact rotates past terminals connected to each spark plug. In this example, each spark plug corresponds to the exposed surface of each of the electrodes. In addition, the present invention includes the means to measure the resistance of the medium in contact with each electrode and cause voltage to be applied only if the resistance exceeds a preselected level.

It should be clearly understood that the invention is not limited to electrically isolated electrode terminals, or even to a plurality of electrode terminals. For example, the array of active electrode terminals may be connected to a single lead that extends through the probe shaft to a power source of high frequency current. Alternatively, the probe may incorporate a single electrode that extends directly through the probe shaft or is connected to a single lead that extends to the power source.

The active electrode(s) are formed over a contact surface on the shaft of the electrosurgical probe. The common (return) electrode surface will be recessed relative to the distal end of the probe and may be recessed within the conduit provided for the introduction of electrically conducting liquid to the site of the target tissue and active electrode(s). In the exemplary embodiment, the shaft will be cylindrical over most of its length, with the contact surface being formed at the distal end of the shaft. In the case of endoscopic applications, the contact surface may be recessed since it helps protect and shield the electrode terminals on the surface while they are being introduced, particularly while being introduced through the working channel of a trocar channel or a viewing scope.

The area of the contact surface can vary widely, and the contact surface can assume a variety of geometries, with particular areas in geometries being selected for specific applications. Active electrode contact surfaces can have areas in the range from 0.25 mm² to 50 mm², usually being from 1 mm² to 20 mm². The geometries can be planar, concave, convex, hemispherical, conical, linear "in-line" array or virtually any other regular or irregular shape. Most commonly, the active electrode(s) will be formed at the distal tip of the electrosurgical probe shaft, frequently being planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures or being linear arrays for use in cutting. Alternatively or additionally, the active electrode(s) may be formed on lateral surfaces of the electrosurgical probe shaft (e.g., in the manner of a spatula), facilitating access to certain body structures in electrosurgical procedures.

During the surgical procedure, the distal end of the probe or the active electrode(s) will be maintained at a small distance away from the target tissue surface. This small spacing allows for the continual resupply of electrically conducting liquid into the interface between the active electrode(s) and the target tissue surface. This continual resupply of the electrically conducting liquid helps to ensure that the thin vapor layer will remain between active electrode(s) and the tissue surface. In addition, dynamic movement of the active electrode(s) over the tissue site allows the electrically conducting liquid to cool the tissue surrounding recently ablated areas to minimize thermal damage to this surrounding tissue. Typically, the active electrode(s) will be about 0.02 to 2 mm from the target tissue and preferably about 0.05 to 0.5 mm during the ablation process. One method of maintaining this space is to translate and/or rotate the probe transversely relative to the tissue, i.e.,

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a light brushing motion, to maintain a thin vaporized layer or region between the active electrode and the tissue. Of course, if coagulation of a deeper region of tissue is necessary (e.g., for sealing a bleeding vessel imbedded within the tissue), it may be desirable to press the active electrode against the tissue to effect joulean heating therein.

Referring to the drawings in detail, wherein like numerals indicate like elements, an electrosurgical system 11 is shown constructed according to the principles of the present invention. Electrosurgical system 11 generally comprises an electrosurgical probe 10 connected to a power supply 28 for providing high frequency voltage to a target tissue 52 and a liquid source 21 for supplying electrically conducting fluid 50 to probe 10.

In an exemplary embodiment as shown in FIG. 1, electrosurgical probe 10 includes an elongated shaft 13 which may be flexible or rigid, with flexible shafts optionally including support cannulas or other structures (not shown). Probe 10 includes a connector 19 at its proximal end and an array 12 of electrode terminals 58 disposed on the distal tip of shaft 13. A connecting cable 34 has a handle 22 with a connector 20 which can be removably connected to connector 19 of probe 10. The proximal portion of cable 34 has a connector 26 to couple probe 10 to power supply 28. The electrode terminals 58 are electrically isolated from each other and each of the terminals 58 is connected to an active or passive control network within power supply 28 by means of a plurality of individually insulated conductors 42 (see FIG. 2C). Power supply 28 has a selection means 30 to change the applied voltage level. Power supply 28 also includes means for energizing the electrodes 58 of probe 10 through the depression of a pedal 39 in a foot pedal 37 positioned close to the user. The foot pedal 37 may also include a second pedal (not shown) for remotely adjusting the energy level applied to electrodes 58. The specific design of a power supply which may be used with the electrosurgical probe of the present invention is described in parent application PCT US 94/051168, the full disclosure of which has previously been incorporated herein by reference.

Referring to FIGS. 2A and 2B, the electrically isolated electrode terminals 58 are spaced-apart over an electrode array surface 82. The electrode array surface 82 and individual electrode terminals 58 will usually have dimensions within the ranges set forth above. In the preferred embodiment, the electrode array surface 82 has a circular cross-sectional shape with a diameter D (FIG. 2B) in the range from 0.3 mm to 10 mm. Electrode array surface 82 may also have an oval shape, having a length L in the range of 1 mm to 20 mm and a width W in the range from 0.3 mm to 7 mm, as shown in FIG. 5. The individual electrode terminals 58 will protrude over the electrode array surface 82 by a distance (H) from 0 mm to 2 mm, preferably from 0 mm to 1 mm (see FIG. 3).

It should be noted that the electrode terminals may be flush with the electrode array surface 82, or the terminals may be recessed from the surface. For example, in dermatological procedures, the electrode terminals 58 may be recessed by a distance from 0.01 mm to 1 mm, preferably 0.01 mm to 0.2 mm. In one embodiment of the invention, the electrode terminals are axially adjustable relative to the electrode array surface 82 so that the surgeon can adjust the distance between the surface and the electrode terminals.

The electrode terminals 58 are preferably composed of a refractory, electrically conductive metal or alloy, such as platinum, titanium, tantalum, tungsten and the like. As shown in FIG. 2B, the electrode terminals 58 are anchored

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in a support matrix 48 of suitable insulating material (e.g., ceramic or glass material, such as alumina, zirconia and the like) which could be formed at the time of manufacture in a flat, hemispherical or other shape according to the requirements of a particular procedure. The preferred support matrix material is alumina, available from Kyocera Industrial Ceramics Corporation, Elk Grove, Ill., because of its high thermal conductivity, good electrically insulative properties, high flexural modulus, resistance to carbon tracking, biocompatibility, and high melting point.

As shown in FIG. 2A, the support matrix 48 is adhesively joined to a tubular support member 78 that extends most or all of the distance between matrix 48 and the proximal end of probe 10. Tubular member 78 preferably comprises an electrically insulating material, such as an epoxy, injection moldable plastic or silicone-based material. In a preferred construction technique, electrode terminals 58 extend through pre-formed openings in the support matrix 48 so that they protrude above electrode array surface 82 by the desired distance H (FIG. 3). The electrodes may then be bonded to the distal surface 82 of support matrix 48, typically by an inorganic sealing material 80. Sealing material 80 is selected to provide effective electrical insulation, and good adhesion to both the ceramic matrix 48 and the platinum or titanium electrode terminals. Sealing material 80 additionally should have a compatible thermal expansion coefficient and a melting point well below that of platinum or titanium and alumina or zirconia, typically being a glass or glass ceramic.

In the embodiment shown in FIGS. 2A and 2B, probe 10 includes a return electrode 56 for completing the current path between electrode terminals 58 and power supply 28. Return electrode 56 is preferably an annular member positioned around the exterior of shaft 13 of probe 10. Return electrode 56 may fully or partially circumscribe tubular support member 78 to form an annular gap 54 therebetween for flow of electrically conducting liquid 50 therethrough, as discussed below. Gap 54 preferably has a width in the range of 0.15 mm to 4 mm. Return electrode 56 extends from the proximal end of probe 10, where it is suitably connected to power supply 28 via connectors 19, 20, to a point slightly proximal of electrode array surface 82, typically about 0.5 to 10 mm and more preferably about 1 to 10 mm.

Return electrode 56 is disposed within an electrically insulative jacket 18, which is typically formed as one or more electrically insulative sheaths or coatings, such as polytetrafluoroethylene, polyimide, and the like. The provision of the electrically insulative jacket 18 over return electrode 56 prevents direct electrical contact between return electrode 56 and any adjacent body structure or the surgeon. Such direct electrical contact between a body structure (e.g., tendon) and an exposed common electrode member 56 could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis.

Return electrode 56 is preferably formed from an electrically conductive material, usually metal, which is selected from the group consisting of stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. The return electrode 56 may be composed of the same metal or alloy which forms the electrode terminals 58 to minimize any potential for corrosion or the generation of electrochemical potentials due to the presence of dissimilar metals contained within an electrically conductive fluid 50, such as isotonic saline (discussed in greater detail below).

As shown in FIG. 2A, return electrode 56 is not directly connected to electrode terminals 58. To complete this cur-

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rent path so that terminals 58 are electrically connected to return electrode 56 via target tissue 52, electrically conducting liquid 50 (e.g., isotonic saline) is caused to flow along liquid paths 83. A liquid path 83 is formed by annular gap 54 between outer return electrode 56 and tubular support member 78. An additional liquid path 83 may be formed between an inner lumen 57 within an inner tubular member 59. However, it is generally preferred to form the liquid path 83 near the perimeter of the probe so that the electrically conducting liquid tends to flow radially inward towards the target site 88 (this preferred embodiment is illustrated in FIGS. 8-19). In the embodiment shown in FIGS. 2-5, the liquid flowing through inner lumen 57 may tend to splash radially outward, drawing electrical current therewith and potentially causing damage to the surrounding tissue.

The electrically conducting liquid 50 flowing through fluid paths 83 provides a pathway for electrical current flow between target tissue 52 and return electrode 56, as illustrated by the current flux lines 60 in FIG. 2A. When a voltage difference is applied between electrode array 12 and return electrode 56, high electric field intensities will be generated at the distal tips of terminals 58 with current flow from array 12 through the target tissue to the return electrode, the high electric field intensities causing ablation of tissue 52 in zone 88.

FIGS. 2C, 3 and 4 illustrate an alternative embodiment of electrosurgical probe 10 which has a return electrode 55 positioned within tubular member 78. Return electrode 55 is preferably a tubular member defining an inner lumen 57 for allowing electrically conducting liquid 50 (e.g., isotonic saline) to flow therethrough in electrical contact with return electrode 55. In this embodiment, a voltage difference is applied between electrode terminals 58 and return electrode 55 resulting in electrical current flow through the electrically conducting liquid 50 as shown by current flux lines 60 (FIG. 3). As a result of the applied voltage difference and concomitant high electric field intensities at the tips of electrode terminals 58, tissue 52 becomes ablated or transected in zone 88.

FIG. 2C illustrates the proximal or connector end 70 of probe 10 in the embodiment of FIGS. 3 and 4. Connector 19 comprises a plurality of individual connector pins 74 positioned within a housing 72 at the proximal end 70 of probe 10. Electrode terminals 58 and the attached insulating conductors 42 extend proximally to connector pins 74 in connector housing 72. Return electrode 55 extends into housing 72, where it bends radially outward to exit probe 10. As shown in FIGS. 1 and 2C, a liquid supply tube 15 removably couples liquid source 21, (e.g., a bag of fluid elevated above the surgical site or having a pumping device), with return electrode 55. Preferably, an insulating jacket 14 covers the exposed portions of electrode 55. One of the connector pins 76 is electrically connected to return electrode 55 to couple electrode 55 to power supply 28 via cable 34. A manual control valve 17 may also be provided between the proximal end of electrode 55 and supply tube 15 to allow the surgical team to regulate the flow of electrically conducting liquid 50.

FIG. 6 illustrates another embodiment of probe 10 where the distal portion of shaft 13 is bent so that electrode terminals extend transversely to the shaft. Preferably, the distal portion of shaft 13 is perpendicular to the rest of the shaft so that electrode array surface 82 is generally parallel to the shaft axis, as shown in FIG. 6. In this embodiment, return electrode 55 is mounted to the outer surface of shaft 13 and is covered with an electrically insulating jacket 18. The electrically conducting fluid 50 flows along flow path 83

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through return electrode 55 and exits the distal end of electrode 55 at a point proximal of electrode surface 82. The fluid is directed exterior of shaft to electrode surface 82 to create a return current path from electrode terminals 58, through target tissue 52, to return electrode 55, as shown by current flux lines 60.

FIG. 7 illustrates another embodiment of the invention where electrosurgical system 11 further includes a liquid supply instrument 64 for supplying electrically conducting fluid 50 between electrode terminals 58 and return electrode 55. Liquid supply instrument 64 comprises an inner tubular member or return electrode 55 surrounded by an electrically insulating jacket 18. Return electrode 55 defines an inner passage 83 for flow of fluid 50. As shown in FIG. 7, the distal portion of instrument 64 is preferably bent so that liquid 50 is discharged at an angle with respect to instrument 64. This allows the surgical team to position liquid supply instrument 64 adjacent electrode surface 82 with the proximal portion of supply instrument 64 oriented at a similar angle to probe 10.

FIGS. 8 and 9 illustrate another embodiment of probe 10 where the return electrode is an outer tubular member 56 that circumscribes support member 78 and conductors 42. Insulating jacket 18 surrounds tubular member 56 and is spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 9). Annular gap preferably has a width in the range of 0.15 mm to 4 mm. Ribs 96 can be formed on either the jacket 18 or member 56. The distal end of return electrode 56 is a distance L_1 from electrode support surface 82. Distance L_1 is preferably about 0.5 to 10 mm and more preferably about 1 to 10 mm. The length L_1 of return electrode 56 will generally depend on the electrical conductivity of the irrigant solution.

As shown in FIG. 8, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with the return electrode) and is discharged through the distal end of gap 54. The liquid 50 is then directed around support member 78 to electrode terminals 58 to provide the current pathway between the electrode terminals and return electrode 56. Since return electrode 56 is proximally recessed with respect to electrode surface 82, contact between the return electrode 56 and surrounding tissue is minimized. In addition, the distance L_1 between the active electrode terminals 58 and the return electrode 56 reduces the risk of current shorting therebetween.

The present invention is not limited to an electrode array disposed on a relatively planar surface at the distal tip of probe 10, as described above. Referring to FIGS. 12-14, an alternative probe 10 includes a pair of electrodes 58a, 58b mounted to the distal end of shaft 13. Electrodes 58a, 58b are electrically connected to power supply as described above and preferably have tips 100a, 100b with a screwdriver or flattened shape. The screwdriver shape provides a greater amount of "edges" to electrodes 58a, 58b, to increase the electric field intensity and current density at the edges and thereby improve the cutting ability as well as the ability to limit bleeding from the incised tissue (i.e., hemostasis).

As shown in FIG. 12, current flows between electrode tips 100a and 100b as indicated by current flux lines 60 to heat the target tissue 52. The surgeon then moves probe 10 transversely across tissue 52 to effect an incision 102 in tissue 52, as shown in FIG. 14.

Other modifications and variations can be made to disclose embodiments without departing from the subject invention as defined in the following claims. For example, shaft 13 of probe 10 may have a variety of configurations

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other than the generally linear shape shown in FIGS. 1-8. For example, shaft 13 may have a distal portion that is angled, in the range of 10° to 30° (FIG. 10) or 90° (FIGS. 11 and 6), to improve access to the operative site of the tissue 52 being ablated or cut (see FIG. 10). A shaft having a 90° angle may be particularly useful for accessing gingiva located in the back portion of the patient's mouth and a shaft having a 10° to 30° bend angle may be useful for accessing gingiva near or in the front of the patient's mouth.

In addition, it should be noted that the invention is not limited to an electrode array comprising a plurality of active electrodes. The invention could utilize a plurality of return electrodes, e.g., in a bipolar array or the like. In addition, depending on other conditions, such as the peak-to-peak voltage, electrode diameter, etc., a single active electrode may be sufficient to develop a vapor layer and induce the discharge of energy to ablate or cut tissue, as described above.

By way of example, FIGS. 21 and 22 illustrate the design of a probe 10 according to the present invention comprising a single active electrode 58 having a tubular geometry. As described above, the return electrode may be an outer tubular member 56 that circumscribes insulated conductor 42 and adhesive bonding material 79 which, in turn, adhesively joins to active electrode support members 48a and 48b. Electrode support members 48a and 48b may be ceramic, glass ceramic or other electrically insulating material which resists carbon or arc tracking. A preferred electrode support member material is alumina. In the example embodiment, a solid rod of alumina forms an inner portion 48b of electrode support member 48 and a hollow tube of alumina forms an outer portion 48a of electrode support member 48. Tubular shaped active electrode 58 may be fabricated using shaped cylinder of this metal comprising an electrically conductive metal, such as platinum, tantalum, tungsten, molybdenum, columbium or alloys thereof. Active electrode 58 is connected to connector 19 (see FIG. 2C) via an insulated lead 108. An electrically insulating jacket 18 surrounds tubular member 56 and may be spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 22). Annular gap 54 preferably has a width in the range of 0.15 to 4 mm. Ribs 96 can be formed on either jacket 18 or tubular member 56. The distal end of the return electrode 56 is a distance L_1 from electrode support surface 82. Distance L_1 is preferably about 0.5 mm to 10 mm and more preferably about 1 to 10 mm. The length L_1 of return electrode 56 will generally depend on the electrical conductivity of the irrigant solution.

As shown in FIG. 21, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with return electrode 56) and is discharged through the distal end of gap 54. The liquid 50 is then directed around electrode support member 48a to electrode terminal 58 to provide the current pathway between electrode terminal 58 and return electrode 56. As described above, the active and return electrodes are connected to voltage supply 28 via cable 34 (see FIG. 1).

FIGS. 23 and 24 illustrate further embodiments of electrosurgical probes according to the present invention. In FIG. 23, a probe 10 comprises a multiplicity of electrodes 58 which converge to a single electrode lead 42. As shown, a central electrode 105 extends to the proximal end of the probe shaft for connection to connector 19 (FIG. 2C). The remainder of the electrodes 58 extend through a portion of the probe shaft and are electrically coupled to central electrode 105 by, for example, a weld, solder joint or crimp connection 100. In FIG. 24, an electrosurgical probe 10

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comprises a single electrode 58 connected to a single electrode lead 42. As described above, the active and return electrodes are connected to voltage supply 28 via cable 34 (see FIG. 1).

Both of the single active electrode configurations depicted in FIGS. 21-24 may be used with the integral supply means and return electrodes described above in FIGS. 2-11, 30 and 31. Alternatively, these probe configurations may be operated in body cavities already containing an electrically conducting liquid 50, obviating the need for either an integral supply of said liquid or an electrically insulating sleeve to form a conduit for supply of the electrically conducting liquid 50. Instead, an electrically insulating covering would be applied to substantially all of the return electrode 56 (other than the proximal portion).

FIG. 15 illustrates the current flux lines associated with an electric field 120 applied between the active and return electrodes 56, 58 when a voltage is applied therebetween. As shown, the electric field intensity is substantially higher in the region 88 at the tip of the electrode 58 because the current flux lines are concentrated in these regions. This high electric field intensity leads to induced molecular breakdown of the target tissue through molecular dissociation. Preferably, the electric field intensity is sufficient to ionize the vaporized electrically conducting liquid 50 in a thin layer 124 between the distal tip 122 of the active electrode 58 and the target tissue 52, as shown in FIG. 16. The vapor layer 124 will usually have a thickness of about 0.02 to 2.0 mm.

As shown in FIG. 16, the electric field ionizes the vapor layer due to the presence of an ionizable species (e.g., sodium) within the vapor layer to create a plasma. This ionization, under optimal conditions, induces the discharge of highly energetic electrons and/or photons from the vapor layer. The photon and/or the energetic electrons cause disintegration of the tissue molecules adjacent to the vapor layer. FIG. 16 illustrates the issuance of bubbles 126 of non-condensable gaseous products resulting from the disintegration of tissue at the target site.

The system and method of the present invention is also useful in dermatological procedures, i.e., surface tissue ablation on the patient's outer skin or epidermis. For example, the probe of the present invention can be used for the removal of tissue abnormalities, pigmentations, such as freckles, tattoos, age or liver spots, birth marks, malignant melanomas, and superficial lentigines in the epidermis, and other unwanted tissue, such as soft fatty tissue, cutaneous angiodyplasia, e.g., skin anglioma, malignant tumor tissue, lumbago (i.e., tissue bulges extending from the vertebrae) or the like. In addition, the probe of the present invention may be used for removing surface layers of the epidermis to provide younger looking skin (tissue rejuvenation) or for incising, dividing and resecting tissue during cosmetic surgery procedures.

FIG. 17 illustrates an exemplary embodiment, where an electrosurgical probe 130 is utilized to remove the surface layers of the epidermis 140. Probe 130 includes a shaft 132 coupled to a proximal handle 134 for holding and controlling shaft 132. Similar to previous embodiments, probe 130 includes an active electrode array 136 at the distal tip of shaft 132, an annular return electrode 138 extending through shaft 132 and proximally recessed from the active electrode array 136 and an annular lumen 142 between return electrode 138 and an outer insulating sheath 144. Probe 130 further includes a liquid supply conduit 146 attached to handle 134 and in fluid communication with lumen 142 and a source of electrically conducting fluid (not shown) for

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delivering the fluid past return electrode 138 to the target site on the epidermis 140. As discussed above, electrode array 136 is preferably flush with the distal end of shaft 132 or distally extended from the distal end by a small distance (on the order of 0.005 inches) so to minimize the depth of ablation. Preferably, the distal end of shaft 132 is beveled to improve access and control of probe 130 while treating the epidermal tissue.

The voltage will preferably be sufficient to establish high electric field intensities between the active electrode array 136 and the epidermal tissue 140 to thereby induce molecular breakdown or disintegration of several cell layers of the epidermal tissue. As described above, a sufficient voltage will be applied to develop a thin layer of vapor within the electrically conducting fluid and to ionize the vaporized layer or region between the active electrode(s) and the target tissue. Energy in the form of photons and/or energetic electrons are discharged from the vapor layer to ablate the epidermal tissue, thereby minimizing necrosis of surrounding tissue and underlying cell layers, such as cell structures in the stratum lucidum and/or stratum granulosum.

FIGS. 18-20 illustrate an exemplary embodiment of another important application of the present invention. As discussed above, the probe of the present invention may be particularly useful for boring a channel through tissue by axially translating the probe towards the tissue as the tissue is disintegrated by the mechanisms discussed above. In the exemplary embodiment, the probe of the present invention is used in a transmyocardial revascularization procedure to form channels from the myocardium to the ventricular cavity to perfuse the myocardium. This procedure is an alternative to coronary artery bypass surgery for treating coronary artery disease. The channels allow oxygen enriched blood flowing into the ventricular cavity from the aorta to directly flow into the myocardium; rather than exiting the heart and then flowing back into the myocardium through the coronary arteries.

As shown in FIG. 18, electrosurgical probe 10 is positioned into one of the ventricular cavities of the heart, in this case, the right ventricle 200. Electrosurgical probe 10 may be introduced into the right ventricle 200 in a variety of procedures that are well known in the art, such as a thoracotomy, sternotomy or minimally invasive procedures. In the representative embodiment, probe 10 is introduced into the vasculature of the patient through a percutaneous penetration and axially translated via a guide catheter 202 through one of the major vessels to the right ventricular cavity 204. A preferred embodiment incorporates a steerable guide catheter 202 which can be externally controlled by the surgeon to direct the distal portion of the guide catheter 202 and probe 10 to the target site(s) in ventricular cavity 204.

Referring to FIG. 19, ventricle wall 206 comprises an epicardium 208, a myocardium 210 and an endocardium 212. In the representative embodiment, probe 10 will form a channel 214 or artificial vessel from the ventricular cavity 206, through the endocardium 212 and into the myocardium 210 to thereby increase myocardial blood flow from the endocardium 212 to the myocardium 210. The location of channel 214 may be selected based on familiar epicardial anatomic landmarks, such as the epicardial branches of the coronary arteries. Guide catheter 202 is positioned adjacent the inner endocardial wall and probe 10 is axially translated so that the active electrode 58 at its distal end is positioned proximate the heart tissue. In this embodiment, the probe includes a single, annular electrode 58 at its distal tip for ablation of the heart tissue. However, it will be readily recognized that the probe may include an array of electrode terminals as described in detail above.

Electrically conducting liquid 50 is delivered through an annular lumen 220 between an annular return electrode 222 and an insulating sheath 224 of the probe. Return electrode 222 is recessed from the distal end of active electrode 58, preferably about 0.025 to 0.050 inches. Alternatively, the return electrode may be positioned on the exterior surface (skin) of the patient, or it may be located nearby on a more proximal position of the probe. Similar to the above embodiments, a high frequency voltage (e.g., 100 kHz) is applied between active electrode(s) 58 and return electrode 222 to establish a current flow therebetween that ablates or disintegrates the heart tissue. The high frequency voltage will preferably be sufficient to vaporize a thin layer of the electrically conducting liquid and to induce the discharge of photon and/or electron energy from the vapor layer to provide cold ablation of the heart tissue.

Ablation of the tissue may be facilitated by axially reciprocating and/or rotating the probe within guide catheter 202 a distance of between about 0.05 to 0.20 inches. This axial reciprocation or rotation allows the electrically conducting liquid 50 to flow over the tissue surface being canalized, thereby cooling this tissue and preventing significant thermal damage to the surrounding tissue cells.

FIG. 20 illustrates an alternative embodiment of the probe of FIG. 1. In this embodiment, the probe 260 includes a central lumen 262 having a proximal end attached to a suitable vacuum source (not shown) and an open distal end 266 for aspirating the target site. The active electrode is preferably a single annular electrode 268 surrounding the open distal end 266 of central lumen 262. Central lumen 262 is utilized to remove the ablation products (e.g., liquids and gases) generated at the target site and excess electrically conductive irrigant during the procedure.

In both of the above embodiments, the present invention provides localized ablation or disintegration of heart tissue to form a revascularization channel 214 of controlled diameter and depth. Usually, the diameter will be in the range of 0.5 mm to 3 mm. Preferably, the radio frequency voltage will be in the range of 400 to 1400 volts peak-to-peak to provide controlled rates of tissue ablation and hemostasis while minimizing the depth of necrosis of tissue surrounding the desired channel. This voltage will typically be applied continuously throughout the procedure until the desired length of the channel 214 is completely formed. However, the heartbeat may be monitored and the voltage applied in pulses that are suitably timed with the contractions (systole) of the heart.

It should be noted that the above embodiment is merely representative and is not intended to limit the invention. For example, the electrosurgical probe can be used to effect a myocardial revascularization channel from the exterior of the heart into the ventricular cavity. In this procedure, the probe will be introduced into the thoracic cavity and positioned adjacent the epicardial layer of one of the ventricular walls via one of a variety of conventional manners. The above electrosurgical procedure will then be performed as the electrode is translated towards the heart until a channel is formed to the ventricular cavity.

The system and method of the present invention may also be useful to efficaciously ablate (i.e., disintegrate) cancer cells and tissue containing cancer cells, such as cancer on the surface of the epidermis, eye, colon, bladder, cervix, uterus and the like. The present invention's ability to completely disintegrate the target tissue can be advantageous in this application because simply vaporizing cancerous tissue may lead to spreading of viable cancer cells (i.e., seeding) to

other portions of the patient's body or to the surgical team in close proximity to the target tissue. In addition, the cancerous tissue can be removed to a precise depth while minimizing necrosis of the underlying tissue.

What is claimed is:

1. A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising:

positioning an electrode terminal into at least close proximity with the target site in the presence of an electrically conductive fluid;

positioning a return electrode within the electrically conductive fluid such that the return electrode is not in contact with the body structure to generate a current flow path between the electrode terminal and the return electrode; and

applying a high frequency voltage difference between the electrode terminal and the return electrode such that an electrical current flows from the electrode terminal, through the region of the target site, and to the return electrode through the current flow path.

2. The method of claim 1 wherein the electric current flows substantially through the electrically conductive fluid while minimizing electric current flow passing through the body structure.

3. The method of claim 1 further comprising immersing the target site within a volume of the electrically conductive fluid and positioning the return electrode within the volume of electrically conductive fluid to generate the current flow path between the electrode terminal and the return electrode.

4. The method of claim 1 further comprising delivering the electrically conductive fluid to the target site.

5. The method of claim 4 wherein the electrode terminal is located on the distal end of a probe, and wherein the delivering step comprises supplying the electrically conductive fluid to a proximal end of an axial lumen within the probe and directing the fluid through a distal end of the axial lumen to the electrode terminal.

6. The method of claim 5 wherein the return electrode is an outer tubular member defining an axial passage between the outer surface of the probe and the inner surface of the outer tubular member, the delivering step including directing the electrically conductive fluid through the axial passage to the distal end of the probe over the electrode terminal.

7. The method of claim 4 further including positioning a distal end of a fluid supply shaft adjacent the electrode terminal, the delivering step comprising directing the electrically conductive fluid through an inner lumen in the fluid supply shaft that is electrically connected to the return electrode and discharging the fluid through an open distal end of the supply shaft towards the electrode terminal.

8. The method of claim 4 wherein the electrode terminal is located on a distal end of a probe and the return electrode is an inner tubular member defining an axial lumen, the delivering step including directing electrically conductive fluid through the axial lumen to the distal end of the probe over the electrode terminal.

9. The method of claim 1 wherein the electrode terminal comprises a single active electrode disposed near the distal end of an instrument shaft.

10. The method of claim 1 wherein the electrode terminal includes an array of electrically isolated electrode terminals disposed near the distal end of an instrument shaft.

11. The method of claim 1 wherein the electrically conductive fluid comprises isotonic saline.

12. The method of claim 1 including independently controlling current flow to the electrode terminal based on

electrical impedance between the electrode terminal and the return electrode.

13. The method of claim 1 wherein the return electrode is spaced from the electrode terminal such that when the electrode terminal is brought adjacent a tissue structure immersed in electrically conductive fluid, the return electrode is spaced from the tissue structure and the electrically conductive fluid completes a conduction path between the electrode terminal and the return electrode.

14. The method of claim 1, wherein the return electrode is located on a distal end of an instrument shaft, further comprising an insulating matrix on the instrument shaft between the return electrode and the electrode terminal, the insulating matrix comprising an inorganic material.

15. The method of claim 14 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

16. The method of claim 14 further comprising applying a sufficient voltage difference between the return electrode and the electrode terminal to effect the electrical breakdown of tissue in the immediate vicinity of the electrode terminal.

17. The method of claim 1 further comprising measuring the temperature at the target site and limiting power delivery to the electrode terminal if the measured temperature exceeds a threshold value.

18. The method of claim 1 further comprising applying a sufficient high frequency voltage difference to vaporize the electrically conductive fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

19. The method of claim 18 wherein at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.

20. The method of claim 18 wherein at least a portion of the energy is in the form of energetic electrons.

21. The method of claim 1 wherein the voltage is in the range from 500 to 1400 volts peak to peak.

22. The method of claim 1 further comprising generating a voltage gradient between the electrode terminal and tissue at the target site, the voltage gradient being sufficient to create an electric field that causes the breakdown of tissue through molecular dissociation or disintegration.

23. A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising:

contacting an active electrode with the body structure in the presence of an electrically conductive fluid;

spacing a return electrode away from the body structure in the presence of the electrically conductive fluid; and

applying a high frequency voltage difference between the active electrode and the return electrode such that an electrical current flows from the active electrode, through the electrically conductive fluid, and to the return electrode.

24. The method of claim 23 wherein the electric current flows substantially through the electrically conductive fluid while minimizing electric current flow passing through the body structure.

25. The method of claim 23 wherein at least a portion of the electric current passes through the body structure.

26. The method of claim 23 further comprising immersing the target site within a volume of the electrically conductive fluid and positioning the return electrode within the volume of electrically conductive fluid to generate a current flow path between the active electrode and the return electrode.

27. The method of claim 23 further comprising delivering the electrically conductive fluid to the target site.

28. The method of claim 27 wherein the active electrode is located on the distal end of a probe, and wherein the delivering step comprises supplying the electrically conductive fluid to a proximal end of an axial lumen within the probe and directing the fluid through a distal end of the axial lumen to the active electrode.

29. The method of claim 27 further including positioning a distal end of a fluid supply shaft adjacent the active electrode, the delivering step comprising directing the electrically conductive fluid through an inner lumen in the fluid supply shaft that is electrically connected to the return electrode and discharging the fluid through an open distal end of the supply shaft towards the active electrode.

30. The method of claim 23 wherein the active electrode comprises a single active electrode disposed near the distal end of an instrument shaft.

31. The method of claim 23 wherein the active electrode includes an array of electrically isolated electrode terminals disposed near the distal end of an instrument shaft.

32. The method of claim 23 wherein the electrically conductive fluid comprises isotonic saline.

33. The method of claim 23 including independently controlling current flow to the active electrode based on electrical impedance between the active electrode and the return electrode.

34. The method of claim 23 wherein the return electrode is spaced from the active electrode such that when the active electrode is brought adjacent a tissue structure immersed in electrically conductive fluid, the return electrode is spaced from the tissue structure and the electrically conductive fluid completes a conduction path between the active electrode and the return electrode.

35. The method of claim 23, wherein the return electrode is located on a distal end of a probe, further comprising an insulating matrix at the distal tip of the probe between the return electrode and the active electrode, the insulating matrix comprising an inorganic material.

36. The method of claim 35 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

37. The method of claim 23 further comprising applying a sufficient voltage difference between the return electrode and the active electrode to effect the electrical breakdown of tissue in the immediate vicinity of the active electrode.

38. The method of claim 23 further comprising measuring the temperature at the target site and limiting power delivery to the active electrode if the measured temperature exceeds a threshold value.

39. The method of claim 23 further comprising applying a sufficient high frequency voltage difference to vaporize the electrically conductive fluid in a thin layer over at least a portion of the active electrode and to induce the discharge of energy to the target site in contact with the vapor layer.

40. The method of claim 39 wherein at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.

41. The method of claim 39 wherein at least a portion of the energy is in the form of energetic electrons.

42. The method of claim 23 wherein the voltage is in the range from 500 to 1400 volts peak to peak.

43. The method of claim 23 further comprising generating a voltage gradient between the active electrode and tissue at the target site, the voltage gradient being sufficient to create an electric field that causes the breakdown of tissue through molecular dissociation or disintegration.

* * * * *

United States Patent [19]
Eggers et al.



US005697882A

[11] Patent Number: 5,697,882
[45] Date of Patent: Dec. 16, 1997

[54] SYSTEM AND METHOD FOR
ELECTROSURGICAL CUTTING AND
ABLATION

5,009,656 4/1991 Reimels 606/48
5,057,105 10/1991 Malone et al. 606/28

(List continued on next page.)

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FOREIGN PATENT DOCUMENTS

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515 867 12/1992 European Pat. Off. A61B 17/36
0 740 926 11/1996 European Pat. Off. A61B 17/39
0 754 437 1/1997 European Pat. Off. A61B 17/39
WO 90/07303 7/1990 WIPO A61B 17/39
WO 92/21278 12/1992 WIPO A61B 5/04
WO 93/13816 7/1993 WIPO A61B 17/36
WO 94/14383 7/1994 WIPO A61B 17/36
WO 97/00646 1/1997 WIPO A61B 17/39
WO 97/00647 1/1997 WIPO A61B 17/39

[21] Appl. No.: 561,958

[22] Filed: Nov. 22, 1995

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 485,219, Jun. 7, 1995,
which is a continuation-in-part of Ser. No. 59,681, May 10,
1993, abandoned, which is a continuation-in-part of Ser. No.
958,977, Oct. 9, 1992, Pat. No. 5,366,443, which is a
continuation-in-part of Ser. No. 817,575, Jan. 7, 1992,
abandoned.

[51] Int. Cl.⁶ A61B 1/00

[52] U.S. Cl. 604/114; 604/22

[58] Field of Search 604/114, 22, 28,
604/49, 113, 41; 606/27-32, 35, 38, 41

OTHER PUBLICATIONS

P.C. Nardella (1989) *SPIE* 1068:42-49 Radio Frequency
Energy and Impedance Feedback.

Rand et al. (1985) *J. Arthro. Surg.* 1:242-246 Effect of
Electrocautery on Fresh Human Articular Cartilage.

Primary Examiner—Manuel Mendez

Attorney, Agent, or Firm—Townsend and Townsend and
Crew LLP

[57]

ABSTRACT

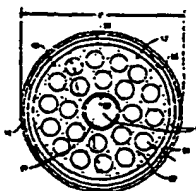
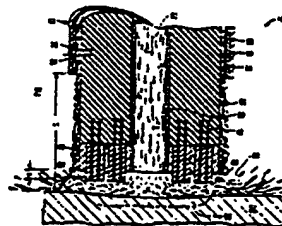
An electrosurgical probe (10) comprises a shaft (13) having
an electrode array (58) at its distal end and a connector (19)
at its proximal end for coupling the electrode array to a high
frequency power supply (28). The shaft includes a return
electrode (56) recessed from its distal end and enclosed
within an insulating jacket (18). The return electrode defines
an inner passage (83) electrically connected to both the
return electrode and the electrode array for passage of an
electrically conducting liquid (50). By applying high fre-
quency voltage to the electrode array and the return
electrode, the electrically conducting liquid generates a
current flow path between the return electrode and the
electrode array so that target tissue may be cut or ablated.
The probe is particularly useful in dry environments, such as
the mouth or abdominal cavity, because the electrically
conducting liquid provides the necessary return current path
between the active and return electrodes.

56 Claims, 17 Drawing Sheets

[56] References Cited

U.S. PATENT DOCUMENTS

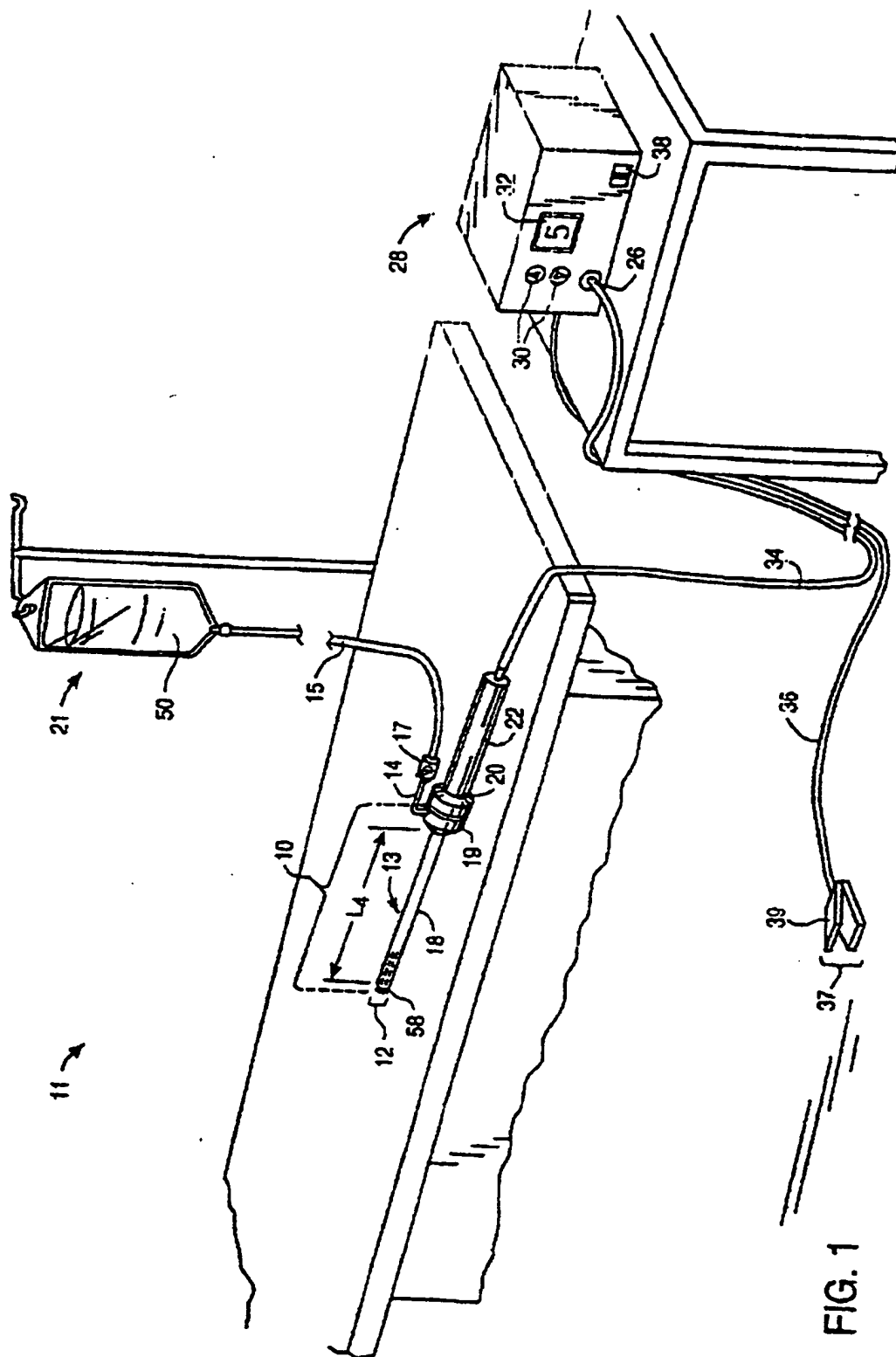
4,202,337 5/1980 Hira et al. 128/303
4,228,800 10/1980 Degler, Jr. et al. 128/303
4,326,529 4/1982 Doss 128/303.1
4,381,007 4/1983 Doss 128/303.1
4,476,862 10/1984 Pao 128/303.17
4,532,924 8/1985 Auth et al. 128/303
4,567,890 2/1986 Ohta et al. 128/303.13
4,593,691 6/1986 Lindstrom et al. 128/303
4,658,817 4/1987 Hardy 128/303
4,674,499 6/1987 Pao 128/303
4,765,331 8/1988 Pazzuzzi et al. 128/303
4,931,047 6/1990 Broadwin et al. 604/22
4,936,301 6/1990 Rezeroth et al. 606/45
4,943,290 7/1990 Rezeroth et al. 606/45
4,967,765 11/1990 Turner et al. 128/785
4,976,711 12/1990 Parins et al. 606/48
4,979,948 12/1990 Goddes et al. 606/33
4,998,933 3/1991 Eggers et al. 606/41



A 18601

U.S. PATENT DOCUMENTS

5,102,410	4/1992	Dressel	606/15	5,290,282	3/1994	Casscells	606/29
5,108,391	4/1992	Flachenecker et al.	606/38	5,304,170	4/1994	Green	606/9
5,195,959	3/1993	Smith	604/34	5,312,395	5/1994	Tan et al.	606/9
5,217,455	6/1993	Tan	606/9	5,336,217	8/1994	Buys et al.	606/9
5,261,410	11/1993	Alfano et al.	128/664	5,370,642	12/1994	Keller	606/9
5,277,201	1/1994	Stern	607/98	5,380,316	1/1995	Aita et al.	606/7
5,281,216	1/1994	Kliock	606/42	5,383,917	1/1995	Desai et al.	607/702
5,282,797	2/1994	Chess	606/9	5,389,096	2/1995	Aita et al.	606/15
5,290,273	3/1994	Tan	606/9	5,423,803	6/1995	Tankovich	606/9
				5,445,634	8/1995	Keller	606/9
				5,569,242	10/1996	Lax et al.	606/42



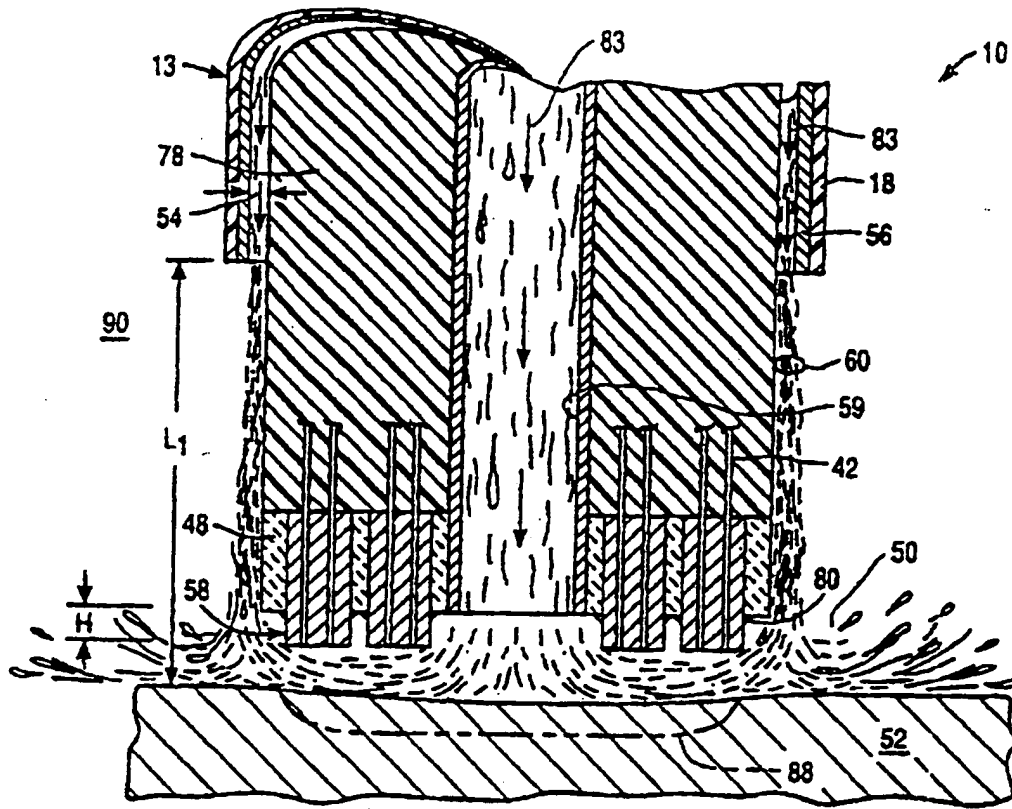


FIG. 2A

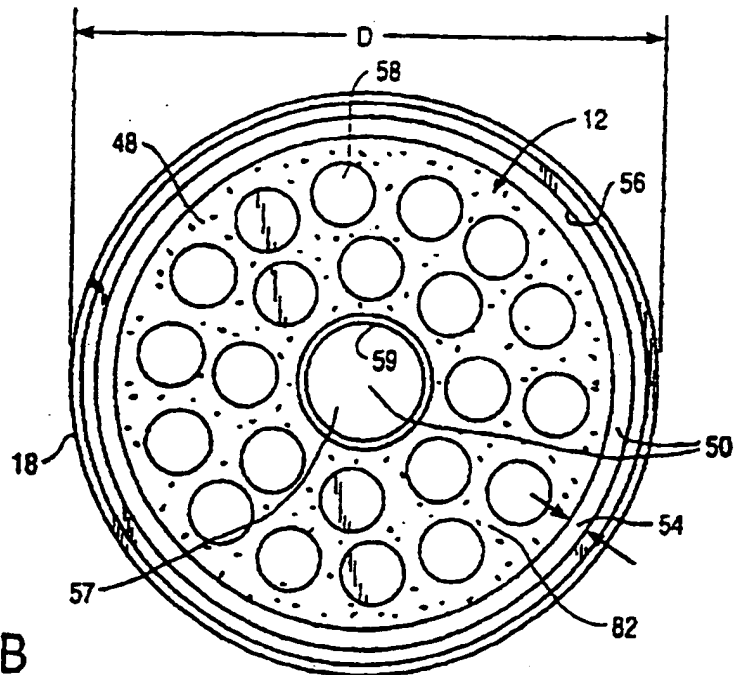


FIG. 2B

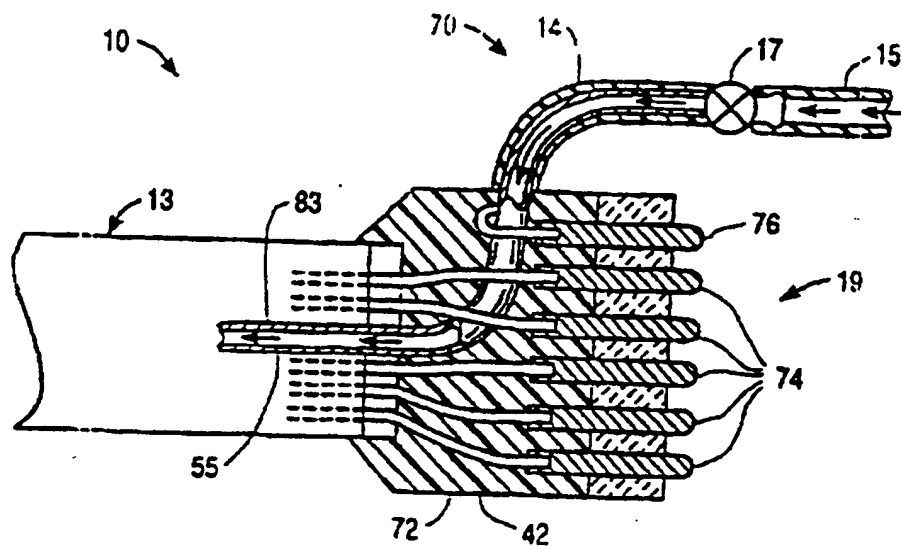


FIG. 2C

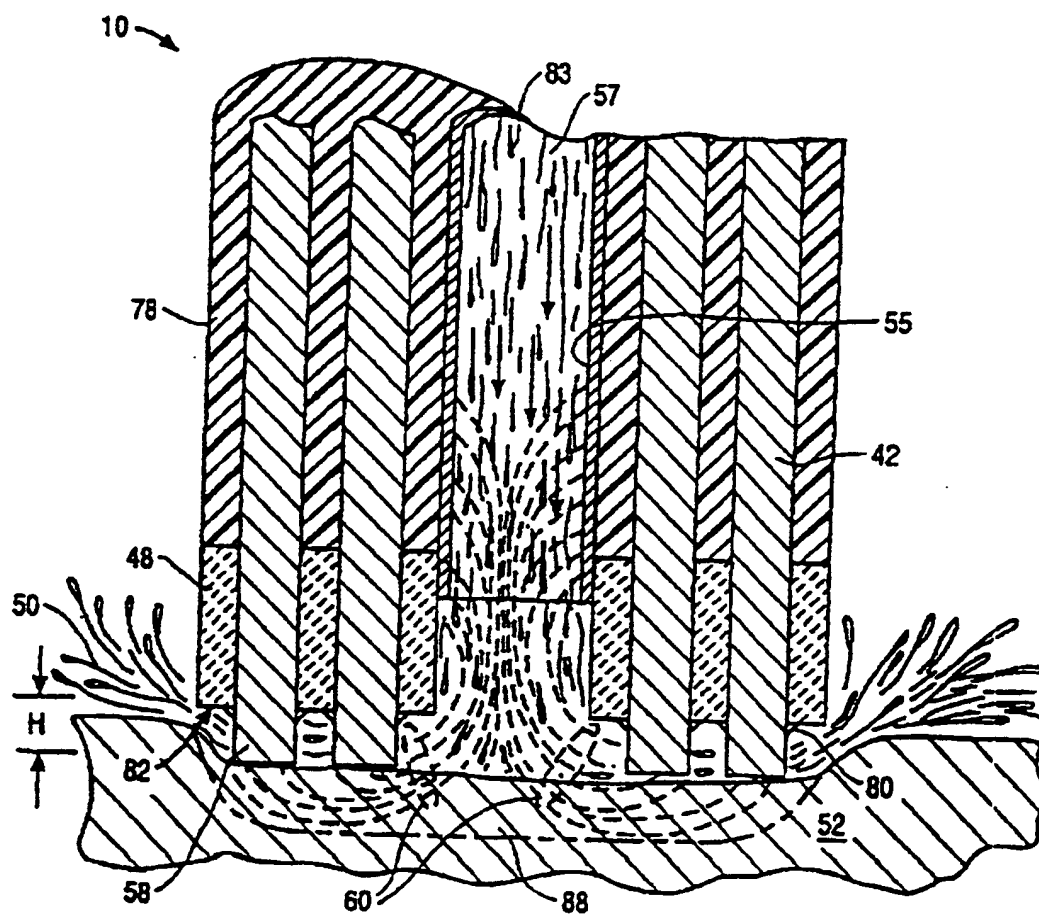


FIG. 3

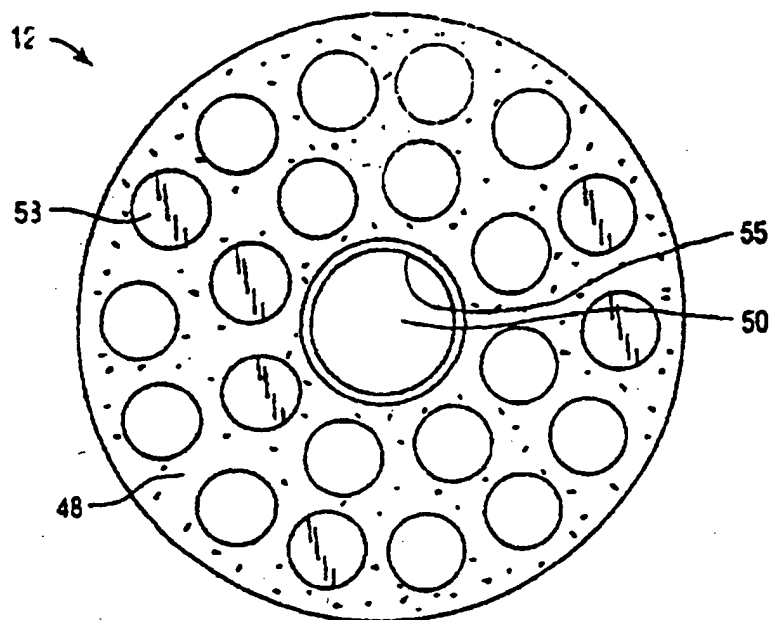


FIG. 4

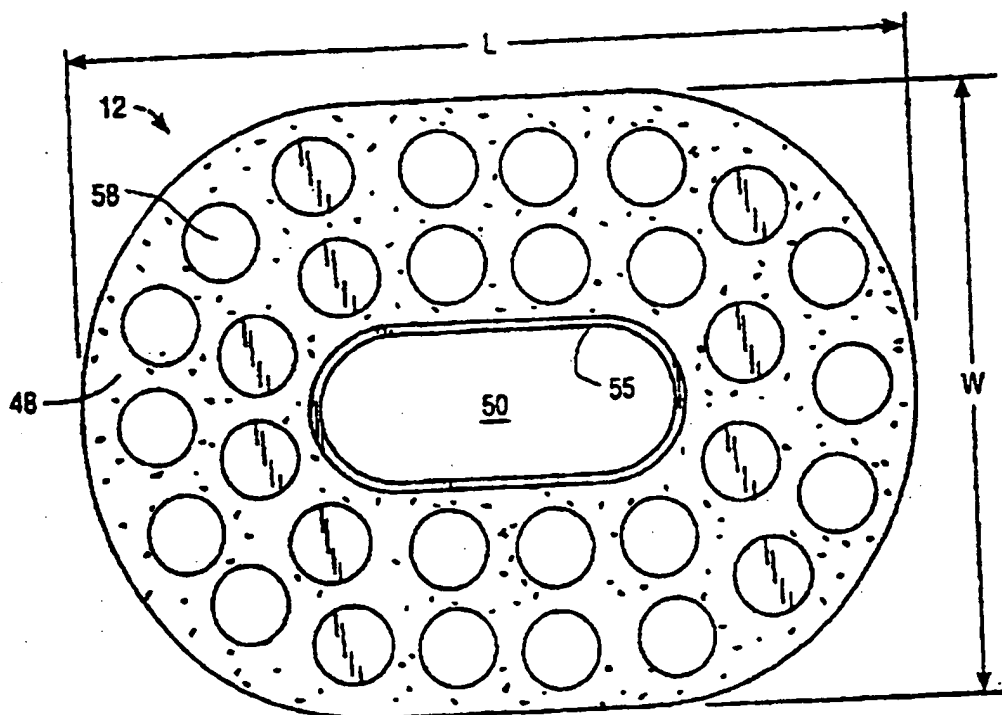


FIG. 5

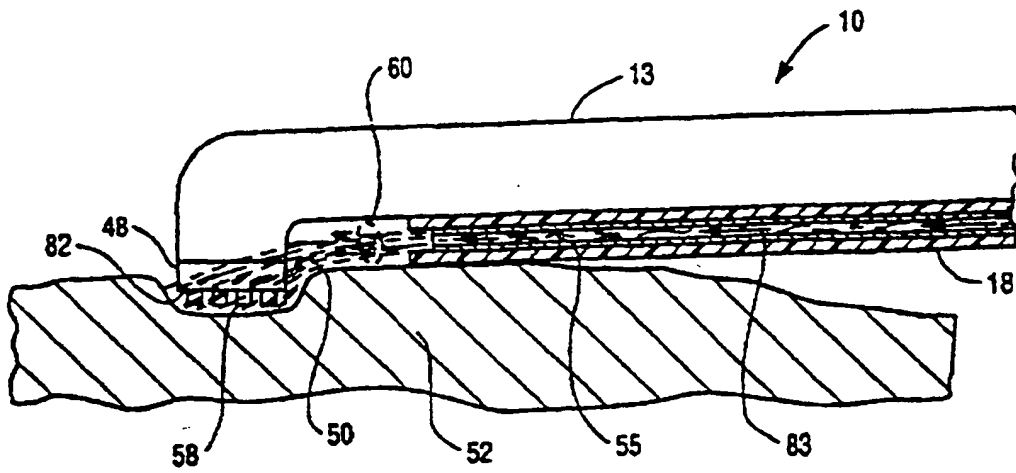


FIG. 6

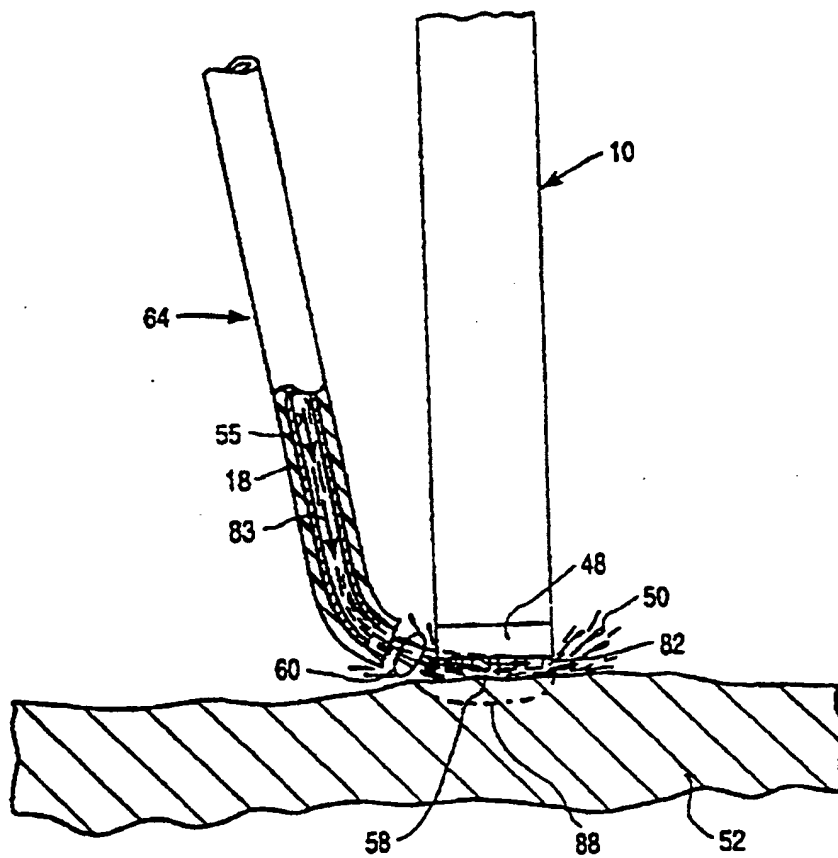


FIG. 7

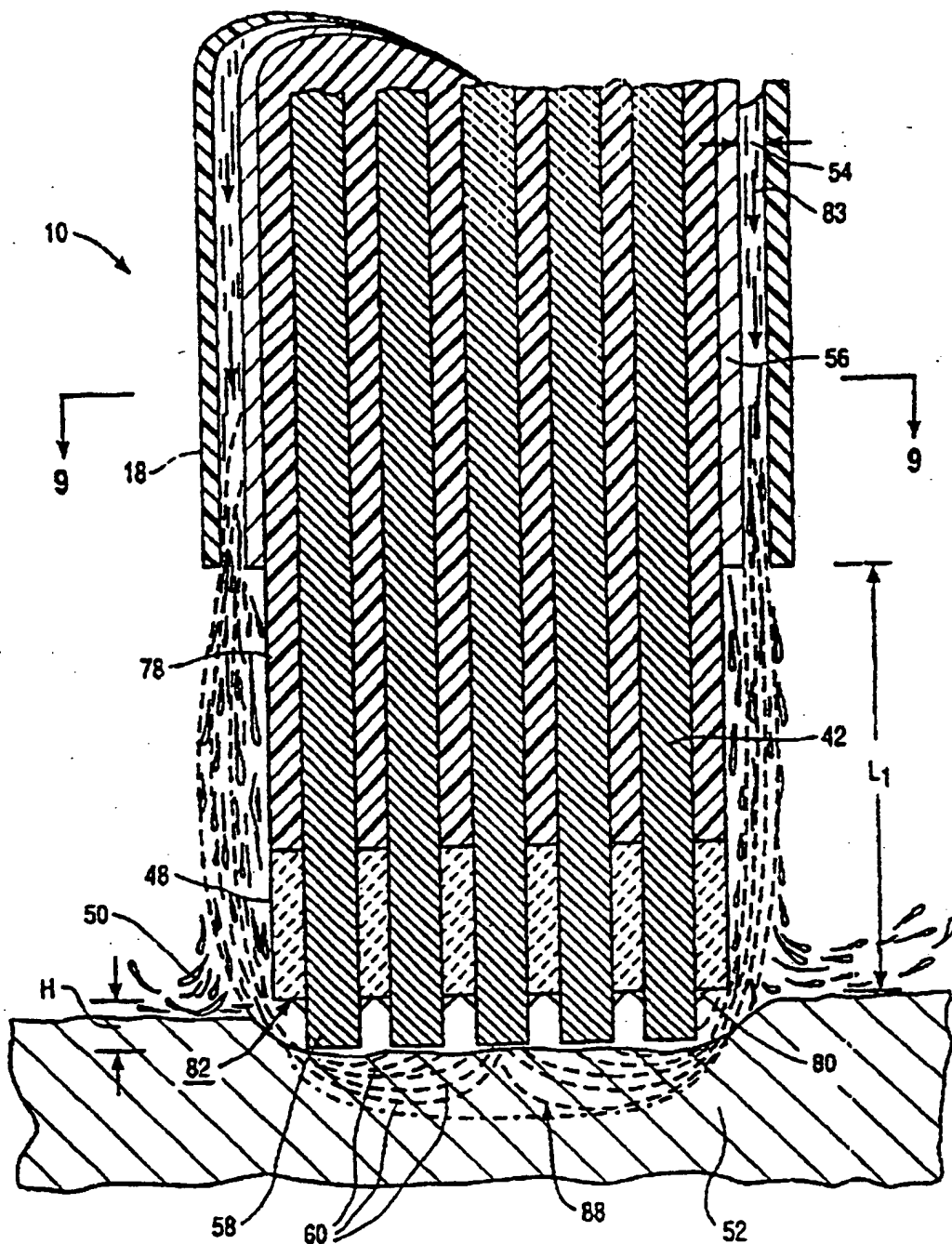


FIG. 8

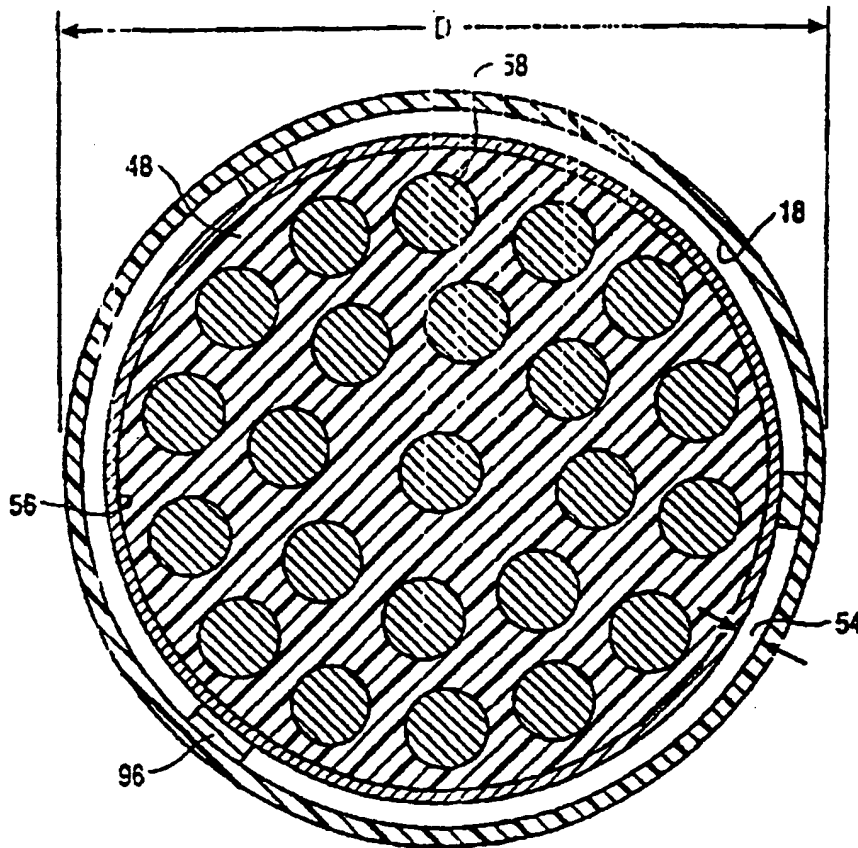


FIG. 9

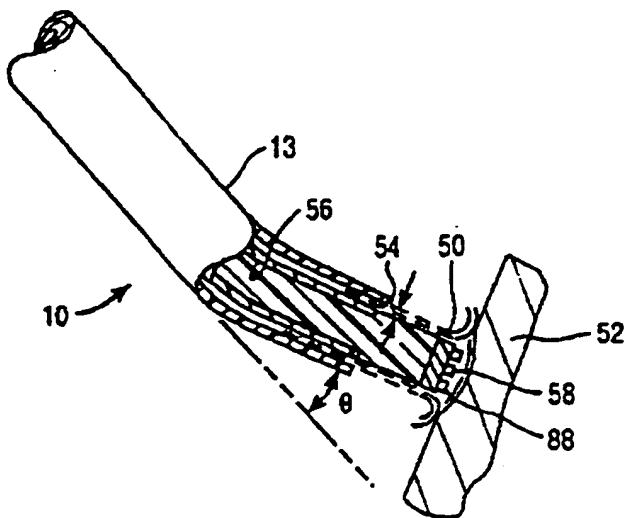


FIG. 10

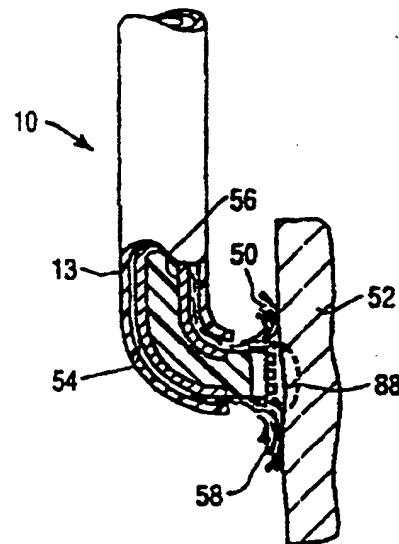


FIG. 11

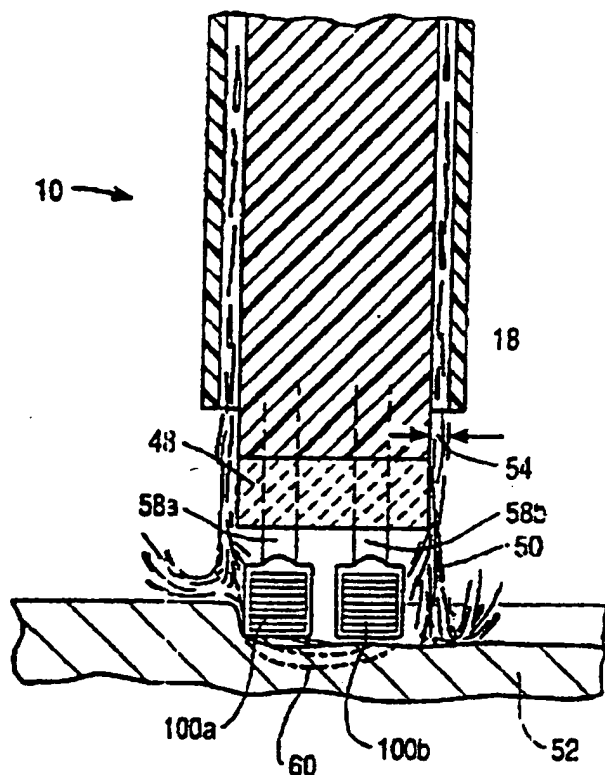


FIG. 12

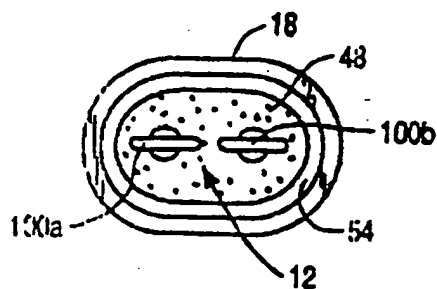


FIG. 13

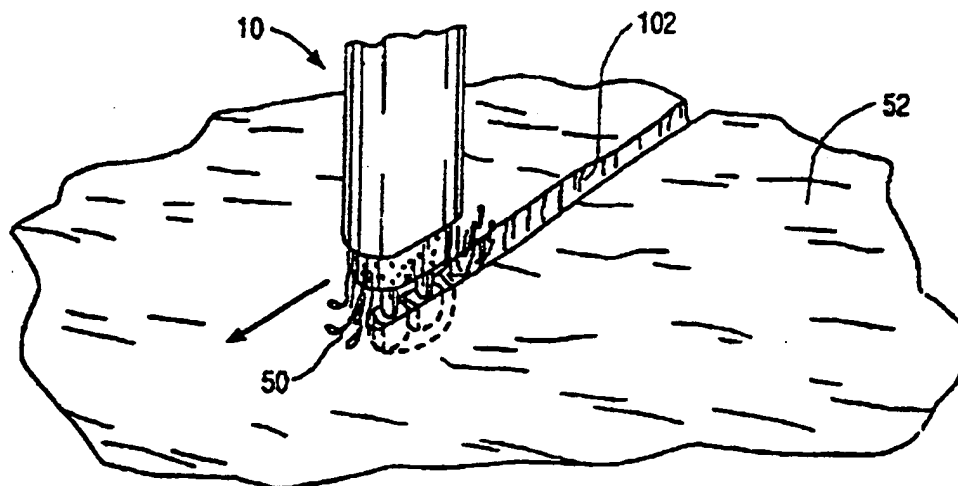


FIG. 14

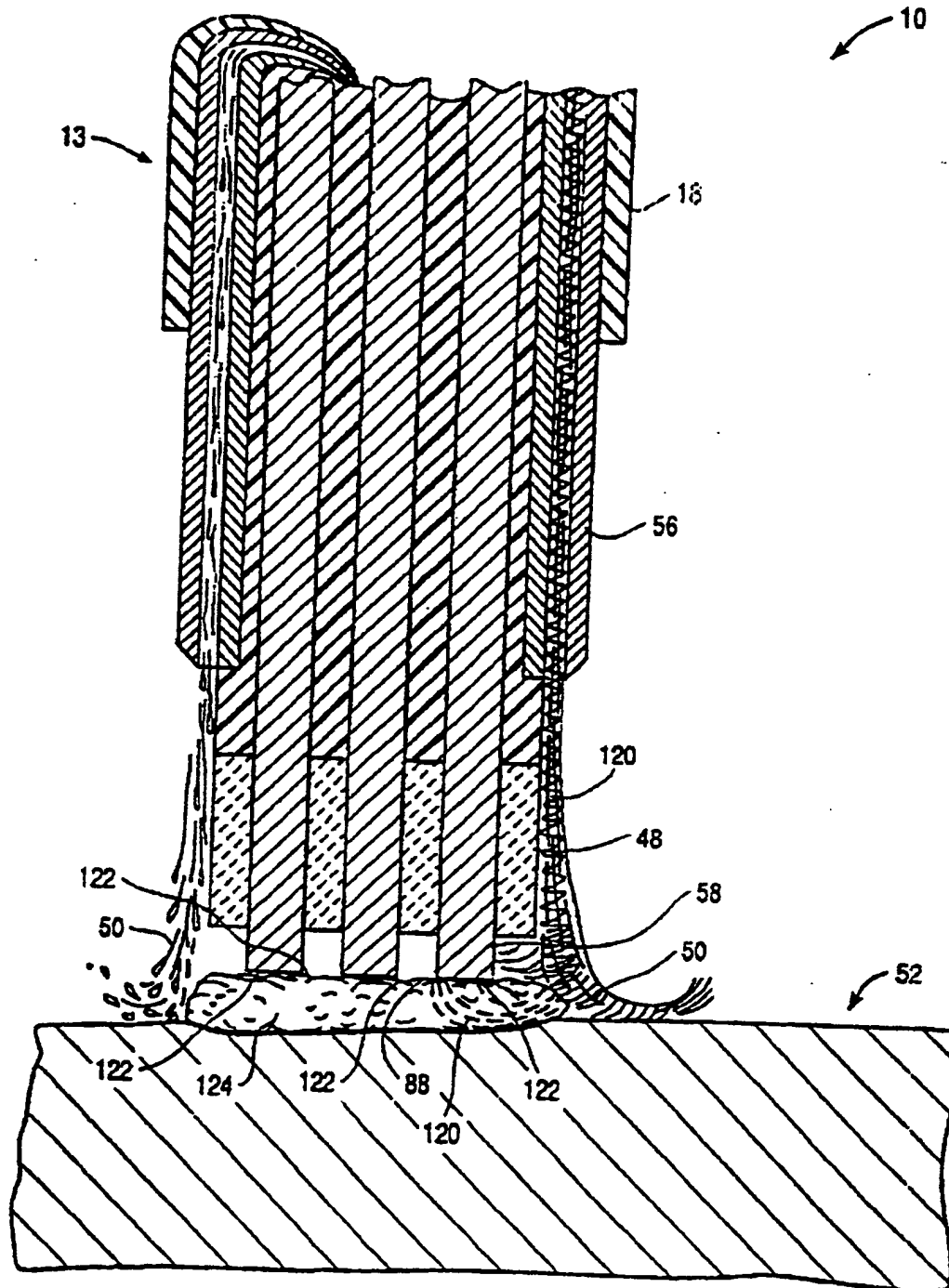


FIG. 15

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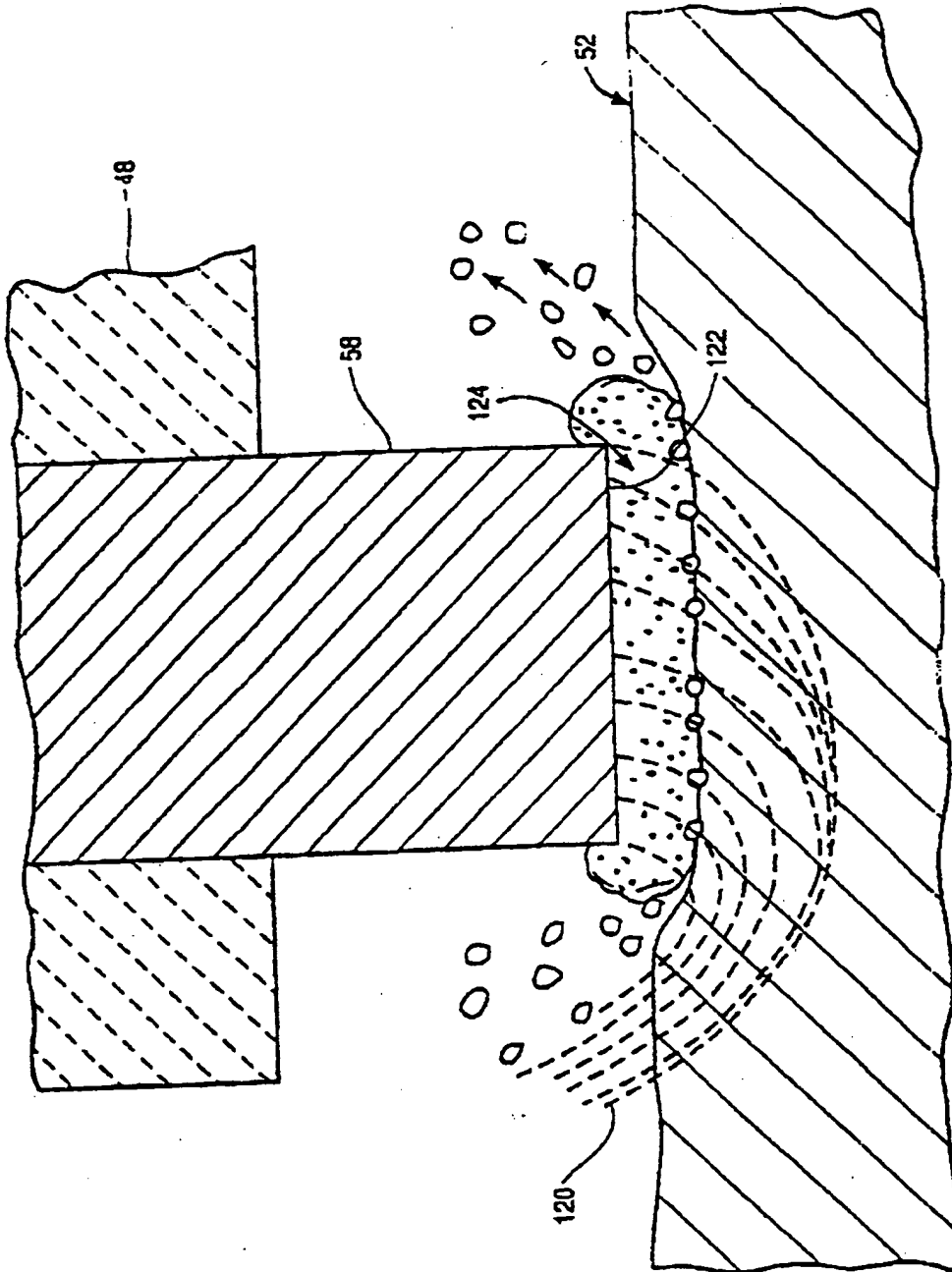
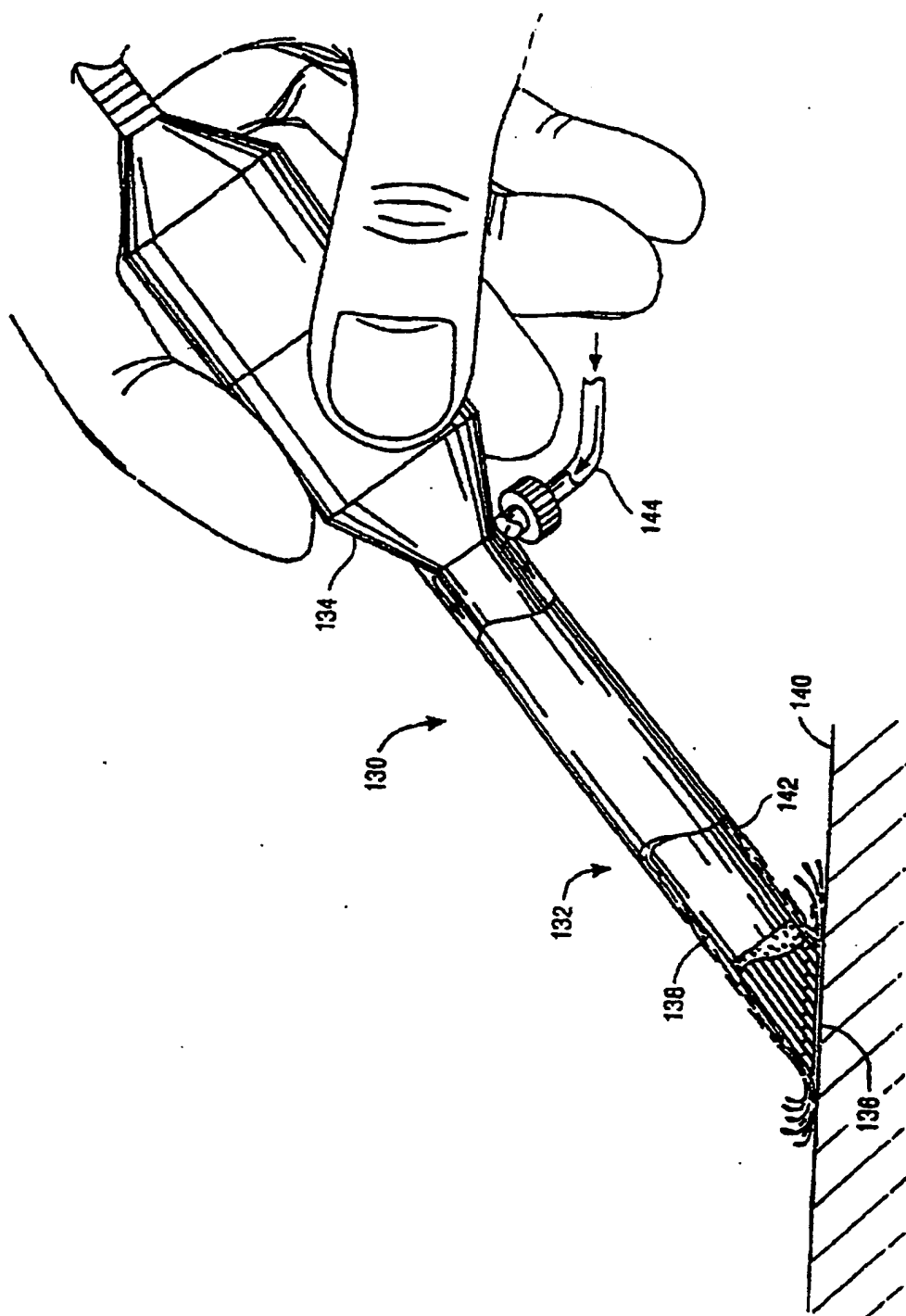


FIG. 16



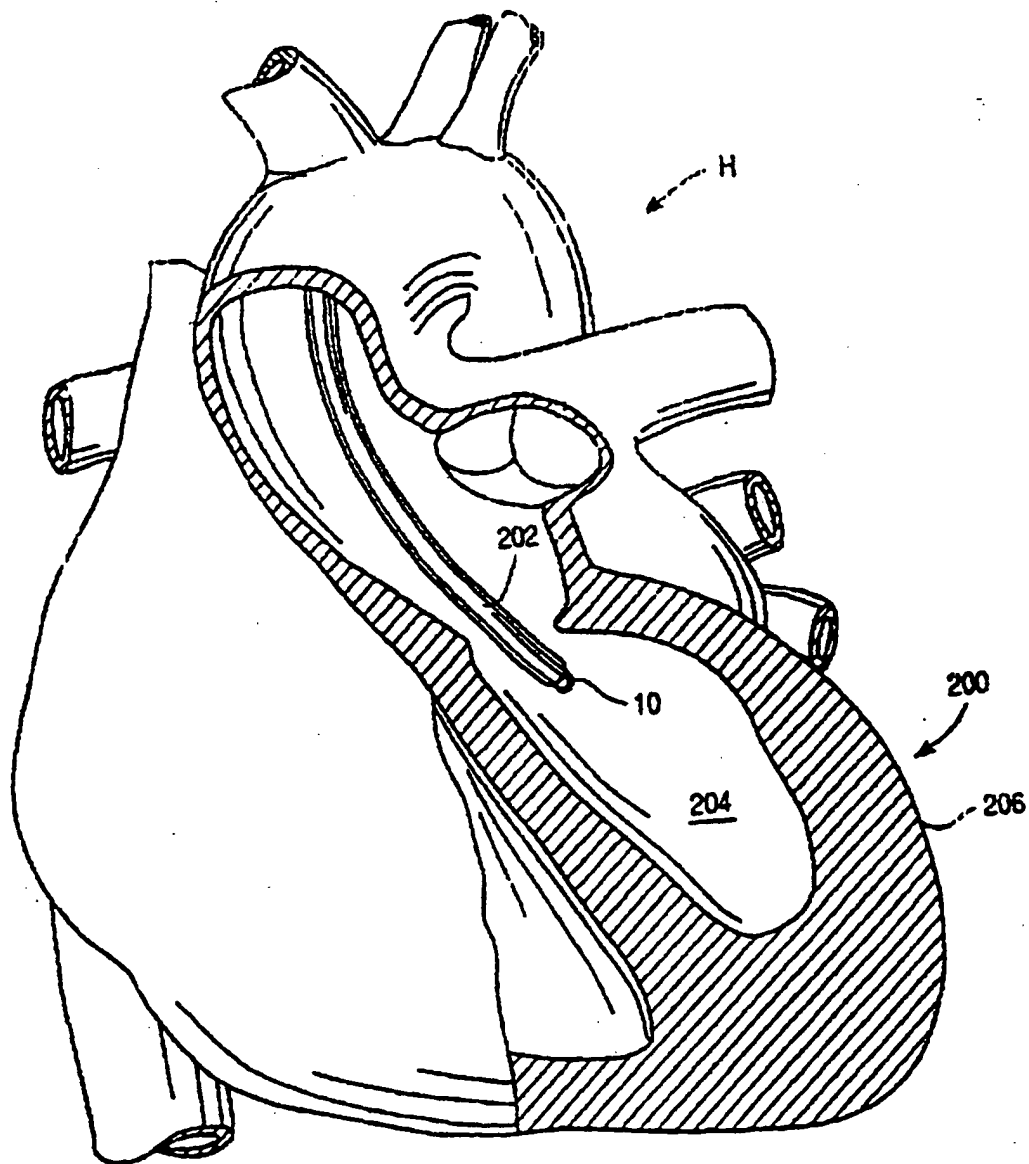


FIG. 18

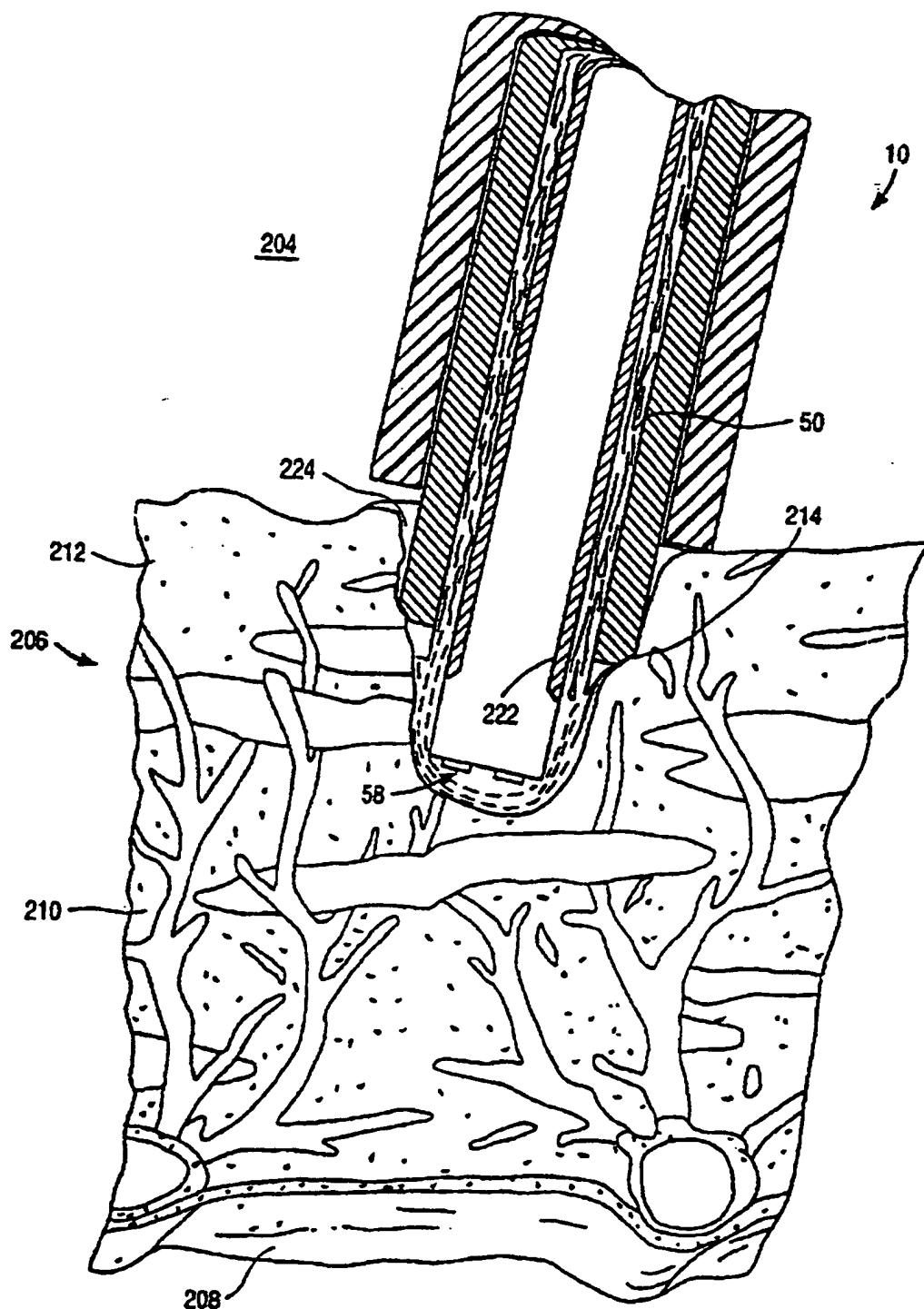


FIG. 19

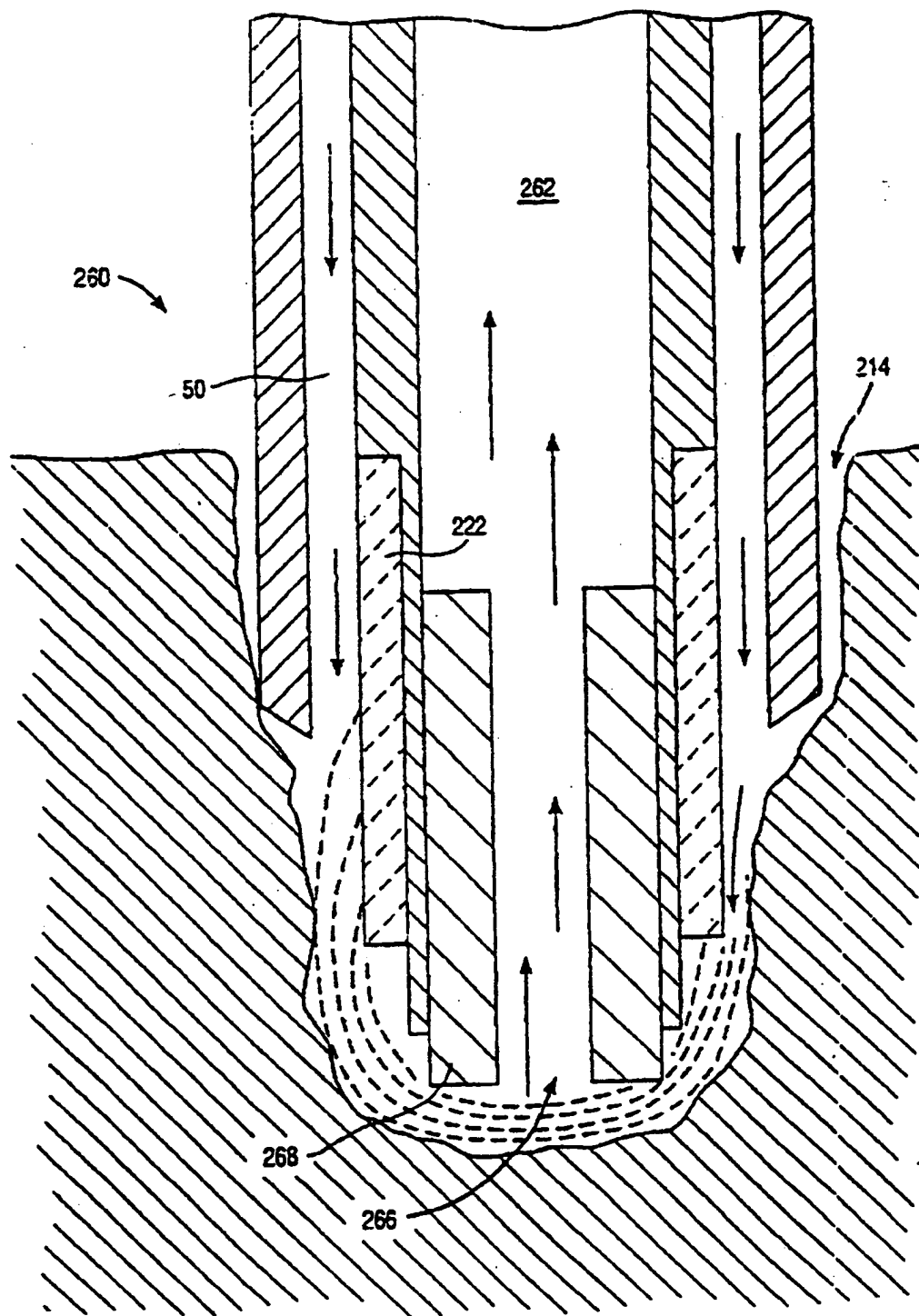
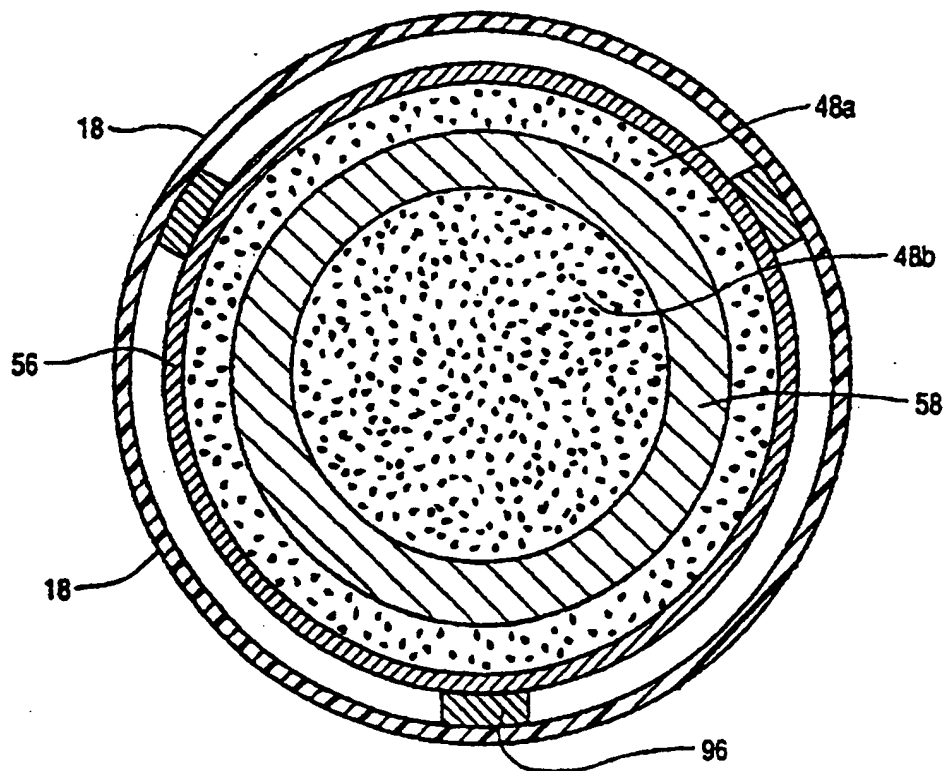
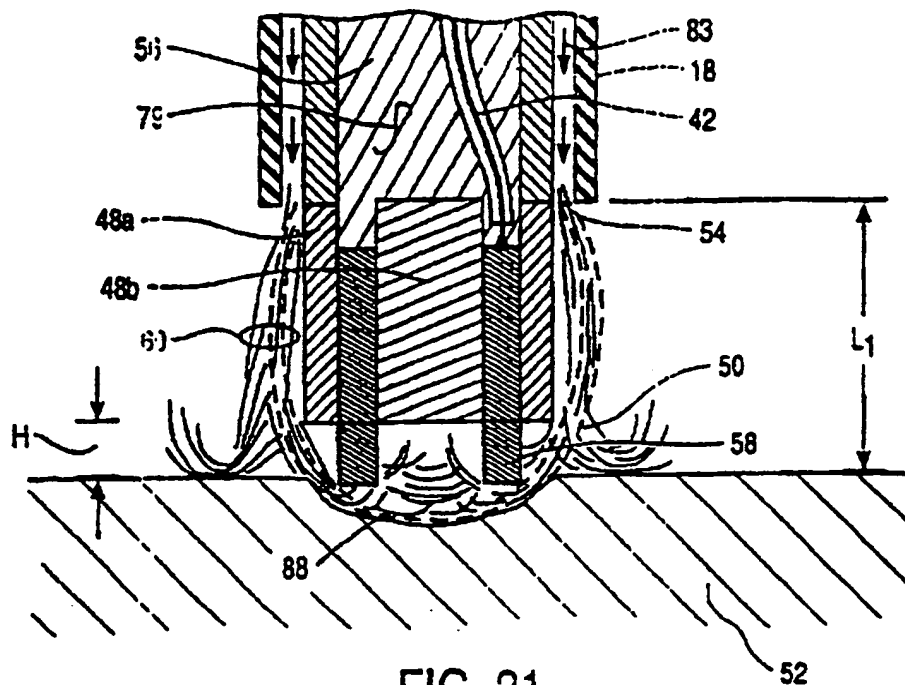


FIG. 20



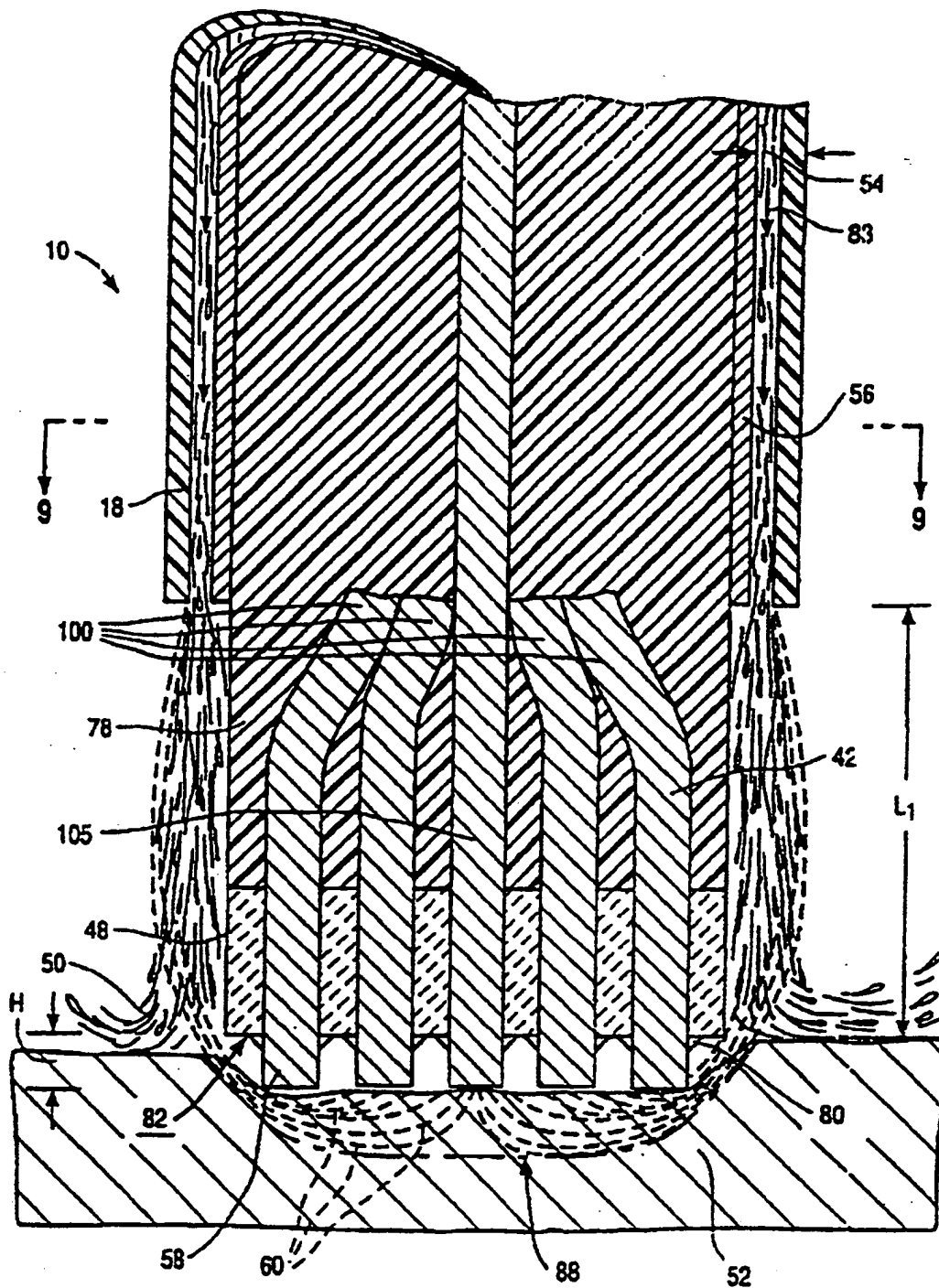


FIG. 23

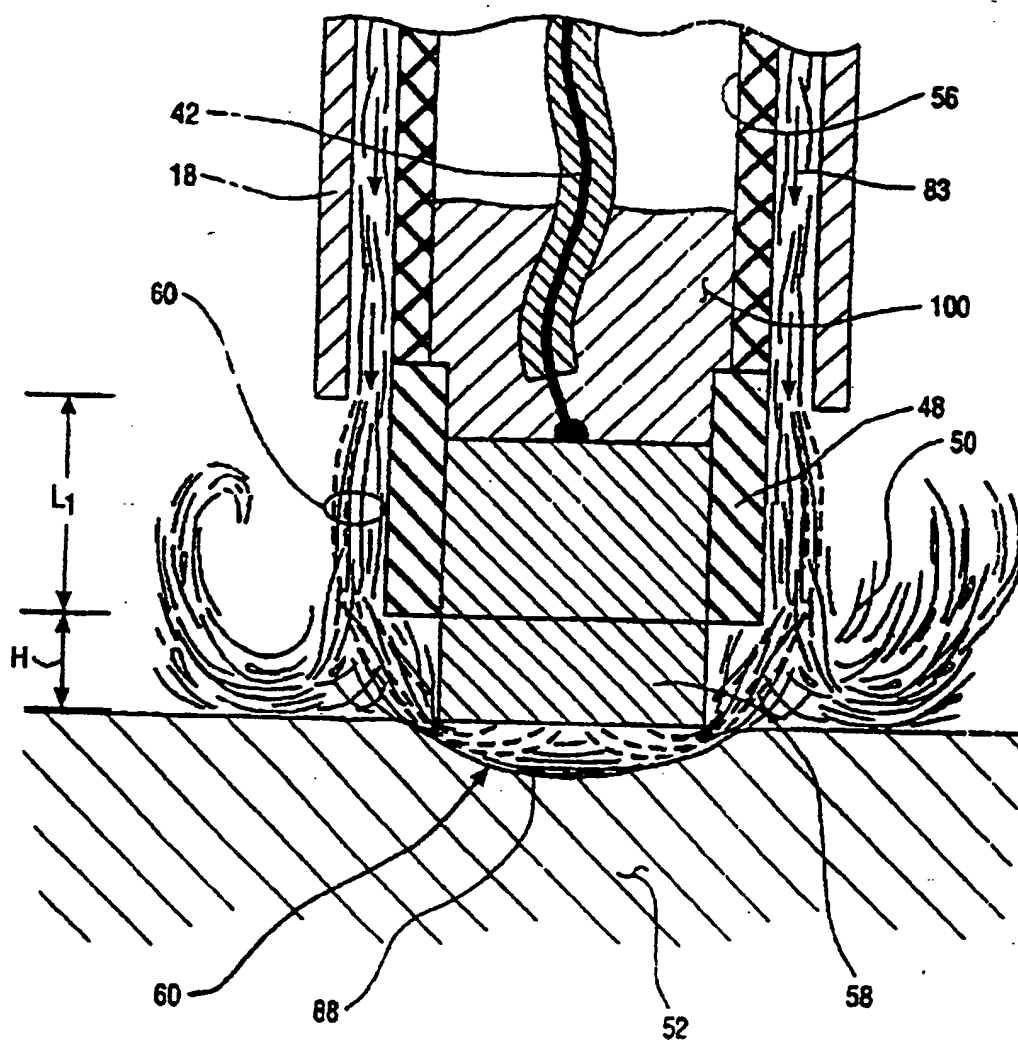


FIG. 24

SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION

BACKGROUND OF THE INVENTION

The present invention is a continuation-in-part of application Ser. No. 08/485,219, filed on Jun. 7, 1995 and still pending, which was a continuation-in-part of PCT International Application, U.S. National Phase Serial No. PCT/US94/05168, filed on May 10, 1994, which was a continuation-in-part of application Ser. No. 08/059,681, filed on May 10, 1993 and now abandoned, which was a continuation-in-part of application Ser. No. 07/958,977, filed on Oct. 9, 1992 now U.S. Pat. No. 5,366,443, which was a continuation-in-part of application Ser. No. 07/817,575, filed on Jan. 7, 1992 now abandoned, the full disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to the field of electrosurgery and, more particularly, to surgical devices and methods which employ high frequency voltage to cut and ablate tissue.

The field of electrosurgery includes a number of loosely related surgical techniques which have in common the application of electrical energy to modify the structure or integrity of patient tissue. Electrosurgical procedures usually operate through the application of very high frequency currents to cut or ablate tissue structures, where the operation can be monopolar or bipolar. Monopolar techniques rely on external grounding of the patient, where the surgical device defines only a single electrode pole. Bipolar devices comprise both electrodes for the application of current between their surfaces.

Electrosurgical procedures and techniques are particularly advantageous since they generally reduce patient bleeding and trauma associated with cutting operations. Current electrosurgical device and procedures, however, suffer from a number of disadvantages. For example, monopolar devices generally direct electric current along a defined path from the exposed or active electrode through the patient's body to the return electrode, which is externally attached to a suitable location on the patient. This creates the potential danger that the electric current will flow through undefined paths in the patient's body, thereby increasing the risk of unwanted electrical stimulation to portions of the patient's body. In addition, since the defined path through the patient's body has a relatively high impedance (because of the large distance or resistivity of the patient's body), large voltage differences must typically be applied between the return and active electrodes in order to generate a current suitable for ablation or cutting of the target tissue. This current, however, may inadvertently flow along body paths having less impedance than the defined electrical path, which will substantially increase the current flowing through these paths, possibly causing damage to or destroying tissue along and surrounding this pathway.

Bipolar electrosurgical devices have an inherent advantage over monopolar devices because the return current path does not flow through the patient. In bipolar electrosurgical devices, both the active and return electrode are typically exposed so that they may both contact tissue, thereby providing a return current path from the active to the return electrode through the tissue. One drawback with this configuration, however, is that the return electrode may cause tissue desiccation or destruction at its contact point

with the patient's tissue. In addition, the active and return electrodes are typically positioned close together to ensure that the return current flows directly from the active to the return electrode. The close proximity of these electrodes generates the danger that the current will short across the electrodes, possibly impairing the electrical control system and/or damaging or destroying surrounding tissue.

The use of electrosurgical procedures (both monopolar and bipolar) in electrically conductive environments can be further problematic. For example, many arthroscopic procedures require flushing of the region to be treated with isotonic saline (also referred to as normal saline), both to maintain an isotonic environment and to keep the field of viewing clear. The presence of saline, which is a highly conductive electrolyte, can also cause shorting of the electrosurgical electrode in both monopolar and bipolar modes. Such shorting causes unnecessary heating in the treatment environment and can further cause non-specific tissue destruction.

Many surgical procedures, such as oral, laparoscopic and open surgical procedures, are not performed with the target tissue submerged under an irrigant. In laparoscopic procedures, such as the resection of the gall bladder from the liver, for example, the abdominal cavity is pressurized with carbon dioxide (pneumoperitoneum) to provide working space for the instruments and to improve the surgeon's visibility of the surgical site. Other procedures, such as the ablation of muscle or gingiva tissue in the mouth, the ablation and necrosis of diseased tissue, or the ablation of epidermal tissue, are also typically performed in a "dry" environment or field (i.e., not submerged under an electrically conducting irrigant).

Present electrosurgical techniques used for tissue ablation also suffer from an inability to control the depth of necrosis in the tissue being treated. Most electrosurgical devices rely on creation of an electric arc between the treating electrode and the tissue being cut or ablated to cause the desired localized heating. Such arcs, however, often create very high temperatures causing a depth of necrosis greater than 500 μm , frequently greater than 800 μm , and sometimes as great as 1700 μm . The inability to control such depth of necrosis is a significant disadvantage in using electrosurgical techniques for tissue ablation, particularly in arthroscopic procedures for ablating and/or reshaping fibrocartilage, articular cartilage, meniscal tissue, and the like.

In an effort to overcome at least some of these limitations of electrosurgery, laser apparatus have been developed for use in arthroscopic and other procedures. Lasers do not suffer from electrical shorting in conductive environments, and certain types of lasers allow for very controlled cutting with limited depth of necrosis. Despite these advantages, laser devices suffer from their own set of deficiencies. In the first place, laser equipment can be very expensive because of the costs associated with the laser light sources. Moreover, those lasers which permit acceptable depths of necrosis (such as eximer lasers, erbium:YAG lasers, and the like) provide a very low volumetric ablation rate, which is a particular disadvantage in cutting and ablation of fibrocartilage, articular cartilage, and meniscal tissue. The holmium:YAG and Nd:YAG lasers provide much higher volumetric ablation rates, but are much less able to control depth of necrosis than are the slower laser devices. The CO_2 lasers provide high rate of ablation and low depth of tissue necrosis, but cannot operate in a liquid-filled cavity.

For these and other reasons, improved systems and methods are desired for the electrosurgical ablation and cutting of

tissue. These systems and methods should be capable of selectively cutting and ablating tissue and other body structures in electrically conductive environments, such as regions filled with blood or irrigated with electrically conductive solutions, such as isotonic saline, and in relatively dry environments, such as those encountered in oral, dermatological, laparoscopic, thoracoscopic and open surgical procedures. Such apparatus and methods should be able to perform cutting and ablation of tissues, while limiting the depth of necrosis and limiting the damage to tissue adjacent to the treatment site.

DESCRIPTION OF THE BACKGROUND ART

Devices incorporating radio frequency electrodes for use in electrosurgical and electrocautery techniques are described in Rand et al. (1985) *J. Arthro. Surg.* 1:242-246 and U.S. Pat. Nos. 5,281,216; 4,943,290; 4,936,301; 4,593,691; 4,228,800; and 4,202,337. U.S. Pat. Nos. 4,943,290 and 4,036,301 describe methods for injecting non-conducting liquid over the tip of a monopolar electrosurgical electrode to electrically isolate the electrode, while energized, from a surrounding electrically conducting irrigant. U.S. Pat. Nos. 5,195,959 and 4,674,499 describe monopolar and bipolar electrosurgical devices, respectively, that include a conduit for irrigating the surgical site.

U.S. Pat. Nos. 5,217,455, 5,423,803, 5,102,410, 5,282,797, 5,290,273, 5,304,170, 5,312,395, 5,336,217 describe laser treatment methods for removing abnormal skin cells, such as pigmentations, lesions, soft tissue and the like. U.S. Pat. Nos. 5,445,634 and 5,370,642 describe methods for using laser energy to divide, incise or resect tissue during cosmetic surgery. U.S. Pat. No. 5,261,410 is directed to a method and apparatus for detecting and removing malignant tumor tissue. U.S. Pat. Nos. 5,380,316, 4,658,817, 5,389,096, PCT application No. WO 94/14383 and European Patent Application No. 0 515 867 describe methods and apparatus for percutaneous myocardial revascularization. These methods and apparatus involve directing laser energy against the heart tissue to form transverse channels through the myocardium to increase blood flow from the ventricular cavity to the myocardium.

SUMMARY OF THE INVENTION

The present invention provides a system and method for selectively applying electrical energy to structures within or on the surface of a patient's body. The system and method allow the surgical team to perform electrosurgical interventions, such as ablation and cutting of body structures, while limiting the depth of necrosis and limiting damage to tissue adjacent the treatment site. The system and method of the present invention are useful for surgical procedures in relatively dry environments, e.g. separation of gall bladder from the liver, ablation and necrosis of diseased tissue, such as fibroid tumors, and dermatological procedures involving surface tissue ablation on the epidermis, such as scar or tattoo removal, tissue rejuvenation and the like. The present invention may also be useful in electrically conducting environments, such as arthroscopic or cystoscopic surgical procedures. In addition, the present invention is useful for canalizing or boring channels or holes through tissue, such as the ventricular wall of the heart during transmyocardial revascularization procedures.

The method of the present invention comprises positioning an electrosurgical probe adjacent the target tissue so that at least one active electrode is brought into close proximity

to the target site. A return electrode is positioned within an electrically conducting liquid, such as isotonic saline, to generate a current flow path between the target site and the return electrode. High frequency voltage is then applied between the active and return electrode through the current flow path created by the electrically conducting liquid in either a bipolar or monopolar manner. The probe may then be translated, reciprocated or otherwise manipulated to cut the tissue or effect the desired depth of ablation.

The current flow path may be generated by submerging the tissue site in an electrical conducting fluid (e.g., arthroscopic surgery and the like) or by directing an electrically conducting liquid along a fluid path past the return electrode and to the target site to generate the current flow path between the target site and the return electrode. This latter method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid), such as open, endoscopic or oral surgery, because the electrically conducting liquid provides a suitable current flow path from the target site to the return electrode. The active electrode is preferably disposed at the distal end of the probe and the return electrode is spaced from the active electrode and enclosed within an insulating sheath. This minimizes exposure of the return electrode to surrounding tissue and minimizes possible shorting of the current between the active and return electrodes. In oral procedures, the probe may be introduced directly into the cavity of the open mouth so that the active electrode is positioned against gingival or mucosal tissue. In endoscopic procedures, the probe will typically be passed through a conventional trocar cannula while viewing of the operative site is provided through the use of a laparoscope disposed in a separate cannula.

In a specific aspect of the invention, the high frequency voltage applied between the active and return electrodes generates high voltage gradients in the vicinity of the probe tip. These high voltage gradients are sufficient to create an electric field at the distal boundary of the active electrode(s) that is sufficiently high to break down the tissue through molecular dissociation or disintegration. The high frequency voltage imparts energy to the target site to ablate a thin layer of tissue without causing substantial tissue necrosis beyond the boundary of the thin layer of tissue ablated. This ablative process can be precisely controlled to effect the volumetric removal of tissue as thin as a few layers of cells with minimal heating of or damage to surrounding or underlying tissue structures.

Applicants believe that this precisely controlled ablation is at least partly caused by the high electric field generated around the tip of the active electrode(s) within the electrically conductive liquid. The electric field vaporizes the electrically conductive liquid into a thin layer over at least a portion of the active electrode surface and then ionizes the vapor layer due to the presence of an ionizable species within the liquid. This ionization and the presence of high electric fields in a low density vaporized layer induces the discharge of highly energetic electrons and photons in the form of ultraviolet energy from the vapor layer. The ultraviolet energy and/or energetic electrons cause disintegration of the tissue molecules adjacent to the vapor layer. This energy discharge can be precisely controlled to effect the volumetric removal of tissue thicknesses ranging from millimeters to a few layers of cells without heating or otherwise damaging surrounding or underlying cell structures.

The active electrode(s) will be spaced away from the target tissue by a suitable distance during the ablation process. This spacing allows for the continual resupply of electrically conducting liquid at the interface between the

active electrode(s) and the target tissue surface. This continual resupply of the electrically conducting liquid helps to ensure that the thin vapor layer or region will remain over at least a portion of the active electrode(s) between the active electrode(s) and the tissue surface. Preferably, the active electrode(s) will be translated and/or rotated transversely relative to the tissue, i.e., in a light brushing motion, to maintain the supply of electrically conducting fluid in the region between the active electrode(s) and the tissue. This dynamic movement of the active electrode(s) over the tissue site also allows the electrically conducting liquid to cool the tissue surrounding recently ablated areas to minimize damage to this surrounding tissue.

The apparatus according to the present invention comprises an electrosurgical probe having a shaft with a proximal end, a distal end, and at least one active electrode at or near the distal end. A connector is provided at or near the proximal end of the shaft for electrically coupling the active electrode to a high frequency voltage source. A return electrode coupled to the voltage source is spaced a sufficient distance from the active electrode to substantially avoid or minimize current shorting therebetween and, in dry environments, to shield the return electrode from tissue at the target site of ablation or from the surgeon. In irrigant flooded environments, such as arthroscopic surgery, the area of the return electrode is sufficiently large to result in low current densities that effectively preclude damage to nearby tissue. The return electrode may be provided integral with the shaft of the probe or it may be separate from the shaft (e.g., on a liquid supply instrument). In both cases, the return electrode defines an inner, annular surface of the pathway for flow of electrically conducting liquid therethrough. The liquid is directed past the surface of the return electrode and over the active electrode to thereby provide a return current flow path between the target tissue site and the return electrode.

The active and return electrodes will preferably be configured such that, upon the application of a sufficient high-frequency voltage, a thin layer of the electrically conducting liquid is vaporized over at least a portion of the active electrode(s) in the region between the active electrode(s) and the target tissue. To accomplish this, the active electrode(s) will be configured such that high electric field densities form at the distal tips of the active electrode(s). By way of example, the present invention may utilize an electrode array of electrode terminals flush with or recessed from or extending from the distal end of the probe. The electrode terminals will preferably have a sufficiently small area, extension (or recession) length from the probe and sharp edges and/or surface asperities such that localized high current densities are promoted on the electrode terminals which, in turn, lead to the formation of a vaporized layer or region over at least a portion of the active electrode(s) followed by the high electric field induced breakdown (i.e., ionization) of ionizable species within the vapor layer or region and the emission of photon and/or electrons of sufficient energy to cause dissociation of molecules within the target tissue.

In an exemplary embodiment, the active electrode(s) are sized and arranged to create localized sources of energy (e.g., point sources or sources with a relatively small effective radius) at the distal tips of the electrode(s) when a sufficiently high frequency voltage is applied to the return and active electrodes. These small localized sources generate intense energy at the distal ends of the electrodes for molecular dissociation or ablation of tissue in contact with or in close proximity to the electrode tips. In addition, since the localized sources have relatively small radii, the energy

flux decreases with the square of the distance from the localized sources so that the tissue at greater distances from the electrode tips are not significantly affected by the energy flux.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the electrosurgical system including an electrosurgical probe, an electrically conducting liquid supply and an electrosurgical power supply constructed in accordance with the principles of the present invention;

FIG. 2A is an enlarged, cross-sectional view of the distal tip of the electrosurgical probe of FIG. 1 illustrating an electrode arrangement suitable for rapid cutting and ablation of tissue structures;

FIG. 2B is an enlarged end view of the distal tip of the electrosurgical probe of FIG. 1;

FIG. 2C is a cross-sectional view of the proximal end of the electrosurgical probe, illustrating an arrangement for coupling the probe to the electrically conducting liquid supply of FIG. 1;

FIG. 3 is a detailed cross-sectional view of an alternative embodiment of the electrosurgical probe of FIG. 1;

FIG. 4 is an end view of the distal end of the electrosurgical probe of FIG. 3;

FIG. 5 is an end view of another embodiment of the electrosurgical probe of FIG. 1;

FIG. 6 is a partial cross-sectional side view of a further embodiment of the electrosurgical probe with the electrode array disposed transversely to the axis of the probe;

FIG. 7 is a partial front cross-sectional view of an electrosurgical probe and an electrically conductive liquid supply shaft illustrating use of the probe and the shaft in ablating target tissue;

FIG. 8 is an enlarged, cross-sectional view of the distal tip of yet another embodiment of the electrosurgical probe of FIG. 1;

FIG. 9 is a detailed end view of the probe of FIG. 8;

FIG. 10 is a side view of an electrosurgical probe having a shaft with an angled distal portion;

FIG. 11 is a side view of an electrosurgical probe having a shaft with a perpendicular distal portion;

FIG. 12 is a schematic view of an electrosurgical probe having two screwdriver-shaped electrodes extending from the distal end;

FIG. 13 is an end view of the probe of FIG. 12;

FIG. 14 illustrates use of the probe of FIG. 12 for the rapid cutting of tissue;

FIG. 15 is a cross-sectional view of the distal tip of the electrosurgical probe, illustrating electric field lines between the active and return electrodes;

FIG. 16 is an enlarged cross-sectional view of the distal tip of the probe of FIG. 15, illustrating a vapor layer formed between the active electrodes and the target tissue;

FIG. 17 is a cross-sectional view of an alternative electrosurgical probe for applying high frequency voltage to epidermal tissue layers;

FIG. 18 is a sectional view of the human heart, illustrating the electrosurgical probe within the ventricular cavity for performing a transmyocardial revascularization procedure;

FIG. 19 is a cross-sectional view of the probe boring a channel through the ventricular wall;

FIG. 20 depicts an alternative embodiment of the probe of FIG. 19 having an inner lumen for aspirating fluid and gases from the transmyocardial channel;

FIG. 21 depicts a distal portion of an alternative embodiment of the probe of FIGS. 2A-2C incorporating a single electrode with a tubular geometry;

FIG. 22 is a cross-sectional view of the distal end of the probe of FIG. 21;

FIG. 23 is a side cross-sectional view of a distal portion of a further embodiment of the probe of FIGS. 2A-2C incorporating a multiplicity of electrodes which converge to a single electrode lead; and

FIG. 24 is a side cross-sectional view of a distal portion of yet another embodiment of the probe of FIGS. 2A-2C incorporating a single electrode connected to a single electrode lead.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention provides a system and method for selectively applying electrical energy to a target location within or on a patient's body, such as solid tissue or the like, particularly including gingival tissues and mucosal tissues located in the mouth or epidermal tissue on the outer skin. In addition, tissues which may be treated by the system and method of the present invention include tumors, abnormal tissues, and the like. The invention may also be used for canalizing or boring channels or holes through tissue, such as the ventricular wall during transmyocardial revascularization procedures. For convenience, the remaining disclosure will be directed specifically to the cutting, shaping or ablation of gingival or mucosal tissue in oral surgical procedures, the surface tissue ablation of the epidermis in dermatological procedures and the canalization of channels through the myocardium of the heart, but it will be appreciated that the system and method can be applied equally well to procedures involving other tissues of the body, as well as to other procedures including open surgery, laparoscopic surgery, thoracoscopic surgery, and other endoscopic surgical procedures.

In addition, the present invention is particularly useful in procedures where the tissue site is flooded or submerged with an electrically conducting fluid, such as isotonic saline. Such procedures, e.g., arthroscopic surgery and the like, are described in detail in co-pending PCT International Application, U.S. National Phase Serial No. PCT/US94/05168, filed on May 10, 1994, the complete disclosure of which has been incorporated herein by reference.

The present invention may use a single active electrode or an electrode array distributed over a distal contact surface of a probe. The electrode array usually includes a plurality of independently current-limited and/or power-controlled electrode terminals to apply electrical energy selectively to the target tissue while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power dissipation into surrounding electrically conductive liquids, such as blood, normal saline, and the like. The electrode terminals may be independently current-limited by isolating the terminals from each other and connecting each terminal to a separate power source that is isolated from the other electrode terminals. Alternatively, the electrode terminals may be connected to each other at either the proximal or distal ends of the probe to form a single wire that couples to a power source.

The electrosurgical probe will comprise a shaft having a proximal end and a distal end which supports an active electrode. The shaft may assume a wide variety of configurations, with the primary purpose being to mechanically support the active electrode and permit the treating physician to manipulate the electrode from a proximal end of the shaft. Usually, the shaft will be a narrow-diameter rod or tube, more usually having dimensions which permit it to be introduced into a body cavity, such as the mouth or the abdominal cavity, through an associated trocar or cannula in a minimally invasive procedure, such as arthroscopic, laparoscopic, thoracoscopic, and other endoscopic procedures. Thus, the shaft will typically have a length of at least 5 cm for oral procedures and at least 10 cm, more typically being 20 cm, or longer for endoscopic procedures. The shaft will typically have a diameter of at least 1 mm and frequently in the range from 1 to 10 mm. Of course, for dermatological procedures on the outer skin, the shaft may have any suitable length and diameter that would facilitate handling by the surgeon.

The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft. Specific shaft designs will be described in detail in connection with the figures hereinafter.

The circumscribed area of the electrode array is in the range from 0.25 mm² to 75 mm², preferably from 0.5 mm² to 40 mm², and will usually include at least two isolated electrode terminals, more usually at least four electrode terminals, preferably at least six electrode terminals, and often 50 or more electrode terminals, disposed over the distal contact surfaces on the shaft. By bringing the electrode array(s) on the contact surface(s) in close proximity with the target tissue and applying high frequency voltage between the array(s) and an additional common or return electrode in direct or indirect contact with the patient's body, the target tissue is selectively ablated or cut, permitting selective removal of portions of the target tissue while desirably minimizing the depth of necrosis to surrounding tissue. In particular, this invention provides a method and apparatus for effectively ablating and cutting tissue which may be located in close proximity to other critical organs, vessels or structures (e.g., teeth, bone) by simultaneously (1) causing electrically conducting liquid to flow between the common and active electrodes, (2) applying electrical energy to the target tissue surrounding and immediately adjacent to the tip of the probe, (3) bringing the active electrode(s) in close proximity with the target tissue using the probe itself, and (4) optionally moving the electrode array axially and/or transversely over the tissue.

In one configuration, each individual electrode terminal in the electrode array is electrically insulated from all other electrode terminals in the array within said probe and is connected to a power source which is isolated from each of the other electrodes in the array or to circuitry which limits or interrupts current flow to the electrode when low resistivity material (e.g., blood or electrically conductive saline irrigant) causes a lower impedance path between the common electrode and the individual electrode terminal. The isolated power sources for each individual electrode may be separate power supply circuits having internal impedance

characteristics which limit power to the associated electrode terminal when a low impedance return path is encountered, may be a single power source which is connected to each of the electrodes through independently actuatable switches or may be provided by independent current limiting elements, such as inductors, capacitors, resistors and/or combinations thereof. The current limiting elements may be provided in the probe, connectors, cable, controller or along the conductive path from the controller to the distal tip. Alternatively, the resistance and/or capacitance may occur on the surface of the active electrode(s) due to oxide layers which form selected electrode terminals (e.g., titanium or a resistive coating on the surface of metal, such as platinum).

The tip region of the probe may be composed of many independent electrode terminals designed to deliver electrical energy in the vicinity of the tip. The selective application of electrical energy to the target tissue is achieved by connecting each individual electrode terminal and the common electrode to a power source having independently controlled or current limited channels. The common electrode may be a tubular member of conductive material proximal to the electrode array at the tip which also serves as a conduit for the supply of the electrically conducting liquid between the active and common electrodes. The application of high frequency voltage between the common electrode and the electrode array results in the generation of high electric field intensities at the distal tips of the electrodes with conduction of high frequency current from each individual electrode terminal to the common electrode. The current flow from each individual electrode terminal to the common electrode is controlled by either active or passive means, or a combination thereof, to deliver electrical energy to the target tissue while minimizing energy delivery to surrounding (non-target) tissue and any conductive fluids which may be present (e.g., blood, electrolytic irrigants such as saline, and the like).

In a preferred aspect, this invention takes advantage of the differences in electrical resistivity between the target tissue (e.g., gingiva, muscle, fascia, tumor, epidermal, heart or other tissue) and the surrounding conductive liquid (e.g., isotonic saline irrigant). By way of example, for any selected level of applied voltage, if the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is isotonic saline irrigant liquid (having a relatively low electrical impedance), the current control means connected to the individual electrode will limit current flow so that the heating of intervening conductive liquid is minimized. On the other hand, if a portion of or all of the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is gingival tissue (having a relatively higher electrical impedance), the current control circuitry or switch connected to the individual electrode will allow current flow sufficient for the deposition of electrical energy and associated ablation or electrical breakdown of the target tissue in the immediate vicinity of the electrode surface.

The application of a high frequency voltage between the common or return electrode and the electrode array for appropriate time intervals effects ablation, cutting or reshaping of the target tissue. The tissue volume over which energy is dissipated (i.e., a high voltage gradient exists) may be precisely controlled, for example, by the use of a multiplicity of small electrodes whose effective diameters range from about 2 mm to 0.01 mm, preferably from about 1 mm to 0.05 mm, and more preferably from about 0.5 mm to 0.1 mm. Electrode areas for both circular and non-circular terminals

will have a contact area (per electrode) below 5 mm², preferably being in the range from 0.0001 mm² to 1 mm², and more preferably from 0.005 mm² to 0.5 mm². The use of small diameter electrode terminals increases the electric field intensity and reduces the extent or depth of tissue necrosis as a consequence of the divergence of current flux lines which emanate from the exposed surface of each electrode terminal. Energy deposition in tissue sufficient for irreversible damage (i.e., necrosis) has been found to be limited to a distance of about one-half to one electrode diameter. This is a particular advantage over prior electrosurgical probes employing single and/or larger electrodes where the depth of tissue necrosis may not be sufficiently limited.

In previous electrosurgical devices, increased power application and ablation rates have been achieved by increasing the electrode area. Surprisingly, with the present invention, it has been found that the total electrode area can be increased (to increase power delivery and ablation rate) without increasing the depth of necrosis by providing multiple small electrode terminals. Preferably, the terminals will be spaced apart by a distance in the range from about one-half diameter to one diameter for optimum power delivery, as discussed below. The depth of necrosis may be further controlled by switching the applied voltage off and on to produce pulses of current, the pulses being of sufficient duration and associated energy density to effect ablation and/or cutting while being turned off for periods sufficiently long to allow for thermal relaxation between energy pulses. In this manner, the energy pulse duration and magnitude and the time interval between energy pulses are selected to achieve efficient rates of tissue ablation or cutting while allowing the temperature of the treated zone of tissue to "relax" or return to normal physiologic temperatures (usually to within 10° C. of normal body temperature [37° C.], preferably to within 5° C.) before the onset of the next energy (current) pulse.

In addition to the above described methods, the applicant has discovered another mechanism for ablating tissue while minimizing the depth of necrosis. This mechanism involves applying a high frequency voltage between the active electrode surface and the return electrode to develop high electric field intensities in the vicinity of the target tissue site. The high electric field intensities lead to electric field induced molecular breakdown of target tissue through molecular dissociation (rather than thermal evaporation or carbonization). In other words, the tissue structure is volumetrically removed through molecular disintegration of complex organic molecules into non-viable atoms and molecules, such as hydrogen, oxides of carbon, hydrocarbons and nitrogen compounds. This molecular disintegration completely removes the tissue structure, as opposed to transforming the tissue material from a solid form directly to a vapor form, as is typically the case with ablation.

The high electric field intensities may be generated by applying a high frequency voltage that is sufficient to vaporize the electrically conducting liquid over at least a portion of the active electrode(s) in the region between the distal tip of the active electrode and the target tissue. Since the vapor layer or vaporized region has a relatively high electrical impedance, it increases the voltage differential between the active electrode tip and the tissue and causes ionization within the vapor layer due to the presence of an ionizable species (e.g., sodium when isotonic saline is the electrically conducting fluid). This ionization, under optimal conditions, induces the discharge of energetic electrons and photons from the vapor layer and to the surface of the target

tissue. This energy may be in the form of energetic photons (e.g., ultraviolet radiation), energetic particles (e.g., electrons) or a combination thereof.

The necessary conditions for forming a vapor layer near the active electrode tip(s), ionizing the atom or atoms within the vapor layer and inducing the discharge of energy from plasma within the vapor layer will depend on a variety of factors, such as: the number of electrode terminals; electrode size and spacing; electrode surface area; asperities and sharp edges on the electrode surfaces; electrode materials; applied voltage and power; current limiting means, such as inductors; electrical conductivity of the fluid in contact with the electrodes; density of the fluid; and other factors. Based on initial experiments, applicants believe that the ionization of atoms within the vapor layer produced in isotonic saline (containing sodium chloride) leads to the generation of energetic photons having wavelengths, by way of example, in the range of 306 to 315 nanometers (ultraviolet spectrum) and 588 to 590 nanometers (visible spectrum). In addition, the free electrons within the ionized vapor layer are accelerated in the high electric fields near the electrode tip(s). When the density of the vapor layer (or within a bubble formed in the electrically conducting liquid) becomes sufficiently low (i.e., less than approximately 10^{20} atoms/cm³ for aqueous solutions), the electron mean free path increases to enable subsequently injected electrons to cause impact ionization within these regions of low density (i.e., vapor layers or bubbles). Energy evolved by the energetic electrons (e.g., 4 to 5 eV) can subsequently bombard a molecule and break its bonds, dissociating a molecule into free radicals, which then combine into final gaseous or liquid species.

The photon energy produces photoablation through photochemical and/or photothermal processes to disintegrate tissue thicknesses as small as several cell layers of tissue at the target site. This photoablation is a "cold" ablation, which means that the photon energy transfers very little heat to tissue beyond the boundaries of the region of tissue ablated. The cold ablation provided by photon energy can be precisely controlled to only affect a thin layer of cells without heating or otherwise damaging surrounding or underlying cells. The depth of necrosis will be typically be about 0 to 400 microns and usually 10 to 200 microns. Applicants believe that the "fragments" of disintegrated tissue molecules carry away much of the energy which is deposited on the surface of the target tissue, thereby allowing molecular disintegration of tissue to occur while limiting the amount of heat transfer to the surrounding tissue.

In addition, other competing mechanisms may be contributing to the ablation of tissue. For example, tissue destruction or ablation may also be caused by dielectric breakdown of the tissue structural elements or cell membranes from the highly concentrated intense electric fields at the tip portions of the electrode(s). According to the teachings of the present invention, the active electrode(s) are sized and have exposed surfaces areas which, under proper conditions of applied voltage, cause the formation of a vaporized region or layer over at least a portion of the surface of the active electrode(s). This layer or region of vaporized electrically conducting liquid creates the conditions necessary for ionization within the vaporized region or layer and the generation of energetic electrons and photons. In addition, this layer or region of vaporized electrically conducting liquid provides a high electrical impedance between the electrode and the adjacent tissue so that only low levels of current flow across the vaporized layer or region into the tissue, thereby minimizing joulean heating in, and associated necrosis of, the tissue.

As discussed above, applicants have found that the density of the electrically conducting liquid at the distal tips of the active electrodes should be less than a critical value to form a suitable vapor layer. For aqueous solutions, such as water or isotonic saline, this upper density limit is approximately 10^{20} atoms/cm³, which corresponds to about 3×10^{-3} grams/cm³. Applicants also believe that once the density in the vapor layer reaches a critical value (e.g., approximately 10^{20} atoms/cm³ for aqueous solutions), electron avalanche occurs. The growth of this avalanche is retarded when the space charge generated fields are on the order of the external field. Spatial extent of this region should be larger than the distance required for an electron avalanche to become critical and for an ionization front to develop. This ionization front develops and propagates across the vapor layer via a sequence of processes occurring in the region ahead of the front, viz. heat by electron injection, lowering of the local liquid density below the critical value and avalanche growth of the charged particle concentration.

Electrons accelerated in the electric field within the vapor layer will apparently become trapped after one or a few scatterings. These injected electrons serve to create or sustain a low density region with a large mean free path to enable subsequently injected electrons to cause impact ionization within these regions of low density. The energy evolved at each recombination is on the order of half of the energy band gap (i.e., 4 to 5 eV). It appears that this energy can be transferred to another electron to generate a highly energetic electron. This second, highly energetic electron may have sufficient energy to bombard a molecule to break its bonds, i.e., dissociate the molecule into free radicals.

The electrically conducting liquid should have a threshold conductivity in order to suitably ionize the vapor layer for the inducement of energetic electrons and photons. The electrical conductivity of the fluid (in units of milliSiemens per centimeter or mS/cm) will usually be greater than 0.2 mS/cm, preferably will be greater than 2 mS/cm and more preferably greater than 10 mS/cm. In an exemplary embodiment, the electrically conductive fluid is isotonic saline, which has a conductivity of about 17 mS/cm. The electrical conductivity of the channel trailing the ionization front should be sufficiently high to maintain the energy flow required to heat the liquid at the ionization front and maintain its density below the critical level. In addition, when the electrical conductivity of the liquid is sufficiently high, ionic pre-breakdown current levels (i.e., current levels prior to the initiation of ionization within the vapor layer) are sufficient to also promote the initial growth of bubbles within the electrically conducting liquid (i.e., regions whose density is less than the critical density).

Asperities on the surface of the active electrode(s) appear to promote localized high current densities which, in turn, promote bubble nucleation at the site of the asperities whose enclosed density (i.e., vapor density) is below the critical density to initiate ionization breakdown within the bubble. Hence, a specific configuration of the present invention creates regions of high current densities on the tips of the electrode(s) (i.e., the surface of the electrode(s) which are to engage and ablate or cut tissue). Regions of high current densities can be achieved via a variety of methods, such as producing sharp edges and corners on the distal tips of the electrodes or vapor blasting, chemically etching or mechanically abrading the distal end faces of the active electrodes to produce surface asperities thereon. Alternatively, the electrode terminals may be specifically designed to increase the edge/surface area ratio of the electrode terminals. For example, the electrode terminal(s) may be hollow tubes

having a distal, circumferential edge surrounding an opening. The terminals may be formed in an array as described above or in a series of concentric terminals on the distal end of the probe. High current densities will be generated around the circumferential edges of the electrode terminals to promote nucleate bubble formation.

The voltage applied between the common electrode and the electrode array will be at high or radio frequency, typically between about 5 kHz and 20 MHz, usually being between about 30 kHz and 2.5 MHz, and preferably being between about 50 kHz and 400 kHz. The RMS (root mean square) voltage applied will usually be in the range from about 5 volts to 1000 volts, preferably being in the range from about 50 volts to 800 volts, and more preferably being in the range from about 100 volts to 400 volts. These frequencies and voltages will result in peak-to-peak voltages and currents that are sufficient to vaporize the electrically conductive liquid and, in turn, create the conditions within the vaporized region which result in high electric fields and emission of energetic photons and/or electrons to ablate tissue. Typically, the peak-to-peak voltage will be in the range of 200 to 2000 volts and preferably in the range of 300 to 1400 volts and more preferably in the range of 700 to 900 volts.

As discussed above, the voltage is usually delivered in a series of voltage pulses with a sufficiently high frequency (e.g., on the order of 5 kHz to 20 MHz) such that the voltage is effectively applied continuously (as compared with e.g., lasers claiming small depths of necrosis, which are generally pulsed about 10 to 20 Hz). In addition, the pulsed duty cycle (i.e., cumulative time in any one-second interval that energy is applied) is on the order of about 50% for the present invention, as compared with lasers which typically have a duty cycle of about 0.0001%.

Applicants believe that the present invention is capable of obtaining high ablation rates with effectively continuous mode operation and high duty cycles because the source of energy emitted from the edges and tips of the small electrode terminals is effectively a point source or a source having a relatively small effective radius. As is well known in the art, the flux emitted from a point source and crossing a boundary in spherical space generally decreases as the square of distance from the source. Thus, the "energy source" of the present invention (i.e., the intense electric field, the energetic photons or the energetic electrons) is highly concentrated by virtue of the geometry of the emitting electrodes and the source of energy at the tips of the electrodes. As a result, only those regions or areas that are very close to the electrode tips or source will be exposed to high energy fluxes. Consequently, ablation will typically only occur in tissue layers effectively in contact or in very close proximity with the tips of the electrodes. The tissue at greater distances from the electrode tips are not significantly affected since the energy flux is too low at these distances to irreversibly affect or damage tissue.

Usually, the current level will be selectively limited or controlled and the voltage applied will be independently adjustable, frequently in response to the resistance of tissues and/or fluids in the pathway between an individual electrode and the common electrode. Also, the applied current level may be in response to a temperature control means which maintains the target tissue temperature with desired limits at the interface between the electrode arrays and the target tissue. The desired tissue temperature along a propagating surface just beyond the region of ablation will usually be in the range from about 40° C. to 100° C., and more usually from about 50° C. to 60° C. The tissue being ablated (and

hence removed from the operation site) immediately adjacent the electrode array may reach even higher temperatures.

The preferred power source of the present invention delivers a high frequency current selectable to generate average power levels ranging from tens of milliwatts to tens of watts per electrode, depending on the target tissue being ablated, the rate of ablation desired or the maximum allowed temperature selected for the probe tip. The power source allows the user to select the current level according to the specific requirements of a particular oral surgery, dermatological procedure, open surgery or other endoscopic surgery procedure.

The power source may be current limited or otherwise controlled so that undesired heating of electrically conductive fluids or other low electrical resistance media does not occur. In a presently preferred embodiment of the present invention, current limiting inductors are placed in series with each independent electrode terminal, where the inductance of the inductor is in the range of 10 uH to 50,000 uH, depending on the electrical properties of the target tissue, the desired ablation rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in co-pending PCT application No. PCT/US94/05168, the complete disclosure of which is incorporated herein by reference. Additionally, current limiting resistors may be selected. Preferably, these resistors will have a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual electrode in contact with a low resistance medium (e.g., saline irrigant), the resistance of the current limiting resistor increases significantly, thereby minimizing the power delivery from said electrode into the low resistance medium (e.g., saline irrigant).

As an alternative to such passive circuit structures, regulated current flow to each electrode terminal may be provided by a multi-channel power supply. A substantially constant current level for each individual electrode terminal within a range which will limit power delivery through a low resistance path, e.g., isotonic saline irrigant, and would be selected by the user to achieve the desired rate of cutting or ablation. Such a multi-channel power supply thus provides a substantially constant current source with selectable current level in series with each electrode terminal, wherein all electrodes will operate at or below the same, user selectable maximum current level. Current flow to all electrode terminals could be periodically sensed and stopped if the temperature measured at the surface of the electrode array exceeds user selected limits. Particular control system designs for implementing this strategy are well within the skill of the art.

Yet another alternative involves the use of one or several power supplies which allow one or several electrodes to be simultaneously energized and which include active control means for limiting current levels below a preselected maximum level. In this arrangement, only one or several electrodes would be simultaneously energized for a brief period. Switching means would allow the next one or several electrodes to be energized for a brief period. By sequentially energizing one or several electrodes, the interaction between adjacent electrodes can be minimized (for the case of energizing several electrode positioned at the maximum possible spacing within the overall envelope of the electrode array) or eliminated (for the case of energizing only a single electrode at any one time). As before, a resistance measurement means may be employed for each electrode prior to the application of power wherein a (measured) low resistance (below some preselected level) will prevent that electrode

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from being energized during a given cycle. By way of example, the sequential powering and control scheme of the present invention would function in a manner similar to an automobile distributor. In this example, an electrical contact rotates past terminals connected to each spark plug. In this example, each spark plug corresponds to the exposed surface of each of the electrodes. In addition, the present invention includes the means to measure the resistance of the medium in contact with each electrode and cause voltage to be applied only if the resistance exceeds a preselected level.

It should be clearly understood that the invention is not limited to electrically isolated electrode terminals, or even to a plurality of electrode terminals. For example, the array of active electrode terminals may be connected to a single lead that extends through the probe shaft to a power source of high frequency current. Alternatively, the probe may incorporate a single electrode that extends directly through the probe shaft or is connected to a single lead that extends to the power source.

The active electrode(s) are formed over a contact surface on the shaft of the electrosurgical probe. The common (return) electrode surface will be recessed relative to the distal end of the probe and may be recessed within the conduit provided for the introduction of electrically conducting liquid to the site of the target tissue and active electrode(s). In the exemplary embodiment, the shaft will be cylindrical over most of its length, with the contact surface being formed at the distal end of the shaft. In the case of endoscopic applications, the contact surface may be recessed since it helps protect and shield the electrode terminals on the surface while they are being introduced, particularly while being introduced through the working channel of a trocar channel or a viewing scope.

The area of the contact surface can vary widely, and the contact surface can assume a variety of geometries, with particular areas in geometries being selected for specific applications. Active electrode contact surfaces can have areas in the range from 0.25 mm² to 50 mm², usually being from 1 mm² to 20 mm². The geometries can be planar, concave, convex, hemispherical, conical, linear "in-line" array or virtually any other regular or irregular shape. Most commonly, the active electrode(s) will be formed at the distal tip of the electrosurgical probe shaft, frequently being planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures or being linear arrays for use in cutting. Alternatively or additionally, the active electrode(s) may be formed on lateral surfaces of the electrosurgical probe shaft (e.g., in the manner of a spatula), facilitating access to certain body structures in electrosurgical procedures.

During the surgical procedure, the distal end of the probe or the active electrode(s) will be maintained at a small distance away from the target tissue surface. This small spacing allows for the continual resupply of electrically conducting liquid into the interface between the active electrode(s) and the target tissue surface. This continual resupply of the electrically conducting liquid helps to ensure that the thin vapor layer will remain between active electrode(s) and the tissue surface. In addition, dynamic movement of the active electrode(s) over the tissue site allows the electrically conducting liquid to cool the tissue surrounding recently ablated areas to minimize thermal damage to this surrounding tissue. Typically, the active electrode(s) will be about 0.02 to 2 mm from the target tissue and preferably about 0.05 to 0.5 mm during the ablation process. One method of maintaining this space is to translate and/or rotate the probe transversely relative to the tissue, i.e.,

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a light brushing motion, to maintain a thin vaporized layer or region between the active electrode and the tissue. Of course, if coagulation of a deeper region of tissue is necessary (e.g., for sealing a bleeding vessel imbedded within the tissue), it may be desirable to press the active electrode against the tissue to effect joulean heating therein.

Referring to the drawings in detail, wherein like numerals indicate like elements, an electrosurgical system 11 is shown constructed according to the principles of the present invention. Electrosurgical system 11 generally comprises an electrosurgical probe 10 connected to a power supply 28 for providing high frequency voltage to a target tissue 52 and a liquid source 21 for supplying electrically conducting fluid 50 to probe 10.

In an exemplary embodiment as shown in FIG. 1, electrosurgical probe 10 includes an elongated shaft 13 which may be flexible or rigid, with flexible shafts optionally including support cannulas or other structures (not shown). Probe 10 includes a connector 19 at its proximal end and an array 12 of electrode terminals 58 disposed on the distal tip of shaft 13. A connecting cable 34 has a handle 22 with a connector 20 which can be removably connected to connector 19 of probe 10. The proximal portion of cable 34 has a connector 26 to couple probe 10 to power supply 28. The electrode terminals 58 are electrically isolated from each other and each of the terminals 58 is connected to an active or passive control network within power supply 28 by means of a plurality of individually insulated conductors 42 (see FIG. 2C). Power supply 28 has a selection means 30 to change the applied voltage level. Power supply 28 also includes means for energizing the electrodes 58 of probe 10 through the depression of a pedal 39 in a foot pedal 37 positioned close to the user. The foot pedal 37 may also include a second pedal (not shown) for remotely adjusting the energy level applied to electrodes 58. The specific design of a power supply which may be used with the electrosurgical probe of the present invention is described in parent application PCT US 94/051168, the full disclosure of which has previously been incorporated herein by reference.

Referring to FIGS. 2A and 2B, the electrically isolated electrode terminals 58 are spaced apart over an electrode array surface 82. The electrode array surface 82 and individual electrode terminals 58 will usually have dimensions within the ranges set forth above. In the preferred embodiment, the electrode array surface 82 has a circular cross-sectional shape with a diameter D (FIG. 2B) in the range from 0.3 mm to 10 mm. Electrode array surface 82 may also have an oval shape, having a length L in the range of 1 mm to 20 mm and a width W in the range from 0.3 mm to 7 mm, as shown in FIG. 5. The individual electrode terminals 58 will protrude over the electrode array surface 82 by a distance (H) from 0 mm to 2 mm, preferably from 0 mm to 1 mm (see FIG. 3).

It should be noted that the electrode terminals may be flush with the electrode array surface 82, or the terminals may be recessed from the surface. For example, in dermatological procedures, the electrode terminals 58 may be recessed by a distance from 0.01 mm to 1 mm, preferably 0.01 mm to 0.2 mm. In one embodiment of the invention, the electrode terminals are axially adjustable relative to the electrode array surface 82 so that the surgeon can adjust the distance between the surface and the electrode terminals.

The electrode terminals 58 are preferably composed of a refractory, electrically conductive metal or alloy, such as platinum, titanium, tantalum, tungsten and the like. As shown in FIG. 2B, the electrode terminals 58 are anchored

in a support matrix 48 of suitable insulating material (e.g., ceramic or glass material, such as alumina, zirconia and the like) which could be formed at the time of manufacture in a flat, hemispherical or other shape according to the requirements of a particular procedure. The preferred support matrix material is alumina, available from Kyocera Industrial Ceramics Corporation, Elk Grove, Ill., because of its high thermal conductivity, good electrically insulative properties, high flexural modulus, resistance to carbon tracking, biocompatibility, and high melting point.

As shown in FIG. 2A, the support matrix 48 is adhesively joined to a tubular support member 78 that extends most or all of the distance between matrix 48 and the proximal end of probe 10. Tubular member 78 preferably comprises an electrically insulating material, such as an epoxy, injection moldable plastic or silicone-based material. In a preferred construction technique, electrode terminals 58 extend through pre-formed openings in the support matrix 48 so that they protrude above electrode array surface 82 by the desired distance H (FIG. 3). The electrodes may then be bonded to the distal surface 82 of support matrix 48, typically by an inorganic sealing material 80. Sealing material 80 is selected to provide effective electrical insulation, and good adhesion to both the ceramic matrix 48 and the platinum or titanium electrode terminals. Sealing material 80 additionally should have a compatible thermal expansion coefficient and a melting point well below that of platinum or titanium and alumina or zirconia, typically being a glass or glass ceramic.

In the embodiment shown in FIGS. 2A and 2B, probe 10 includes a return electrode 56 for completing the current path between electrode terminals 58 and power supply 28. Return electrode 56 is preferably an annular member positioned around the exterior of shaft 13 of probe 10. Return electrode 56 may fully or partially circumscribe tubular support member 78 to form an annular gap 54 therebetween for flow of electrically conducting liquid 50 therethrough, as discussed below. Gap 54 preferably has a width in the range of 0.15 mm to 4 mm. Return electrode 56 extends from the proximal end of probe 10, where it is suitably connected to power supply 28 via connectors 19, 20, to a point slightly proximal of electrode array surface 82, typically about 0.5 to 10 mm and more preferably about 1 to 10 mm.

Return electrode 56 is disposed within an electrically insulative jacket 18, which is typically formed as one or more electrically insulative sheaths or coatings, such as polytetrafluoroethylene, polyimide, and the like. The provision of the electrically insulative jacket 18 over return electrode 56 prevents direct electrical contact between return electrode 56 and any adjacent body structure or the surgeon. Such direct electrical contact between a body structure (e.g., tendon) and an exposed common electrode member 56 could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis.

Return electrode 56 is preferably formed from an electrically conductive material, usually metal, which is selected from the group consisting of stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. The return electrode 56 may be composed of the same metal or alloy which forms the electrode terminals 58 to minimize any potential for corrosion or the generation of electrochemical potentials due to the presence of dissimilar metals contained within an electrically conductive fluid 50, such as isotonic saline (discussed in greater detail below).

As shown in FIG. 2A, return electrode 56 is not directly connected to electrode terminals 58. To complete this cur-

rent path so that terminals 58 are electrically connected to return electrode 56 via target tissue 52, electrically conducting liquid 50 (e.g., isotonic saline) is caused to flow along liquid paths 83. A liquid path 83 is formed by annular gap 54 between outer return electrode 56 and tubular support member 78. An additional liquid path 83 may be formed between an inner lumen 57 within an inner tubular member 59. However, it is generally preferred to form the liquid path 83 near the perimeter of the probe so that the electrically conducting liquid tends to flow radially inward towards the target site 88 (this preferred embodiment is illustrated in FIGS. 8-19). In the embodiment shown in FIGS. 2-5, the liquid flowing through inner lumen 57 may tend to splash radially outward, drawing electrical current therewith and potentially causing damage to the surrounding tissue.

The electrically conducting liquid 50 flowing through fluid paths 83 provides a pathway for electrical current flow between target tissue 52 and return electrode 56, as illustrated by the current flux lines 60 in FIG. 2A. When a voltage difference is applied between electrode array 12 and return electrode 56, high electric field intensities will be generated at the distal tips of terminals 58 with current flow from array 12 through the target tissue to the return electrode, the high electric field intensities causing ablation of tissue 52 in zone 88.

FIGS. 2C, 3 and 4 illustrate an alternative embodiment of electrosurgical probe 10 which has a return electrode 55 positioned within tubular member 78. Return electrode 55 is preferably a tubular member defining an inner lumen 57 for allowing electrically conducting liquid 50 (e.g., isotonic saline) to flow therethrough in electrical contact with return electrode 55. In this embodiment, a voltage difference is applied between electrode terminals 58 and return electrode 55 resulting in electrical current flow through the electrically conducting liquid 50 as shown by current flux lines 60 (FIG. 3). As a result of the applied voltage difference and concomitant high electric field intensities at the tips of electrode terminals 58, tissue 52 becomes ablated or transected in zone 88.

FIG. 2C illustrates the proximal or connector end 70 of probe 10 in the embodiment of FIGS. 3 and 4. Connector 19 comprises a plurality of individual connector pins 74 positioned within a housing 72 at the proximal end 70 of probe 10. Electrode terminals 58 and the attached insulating conductors 42 extend proximally to connector pins 74 in connector housing 72. Return electrode 55 extends into housing 72, where it bends radially outward to exit probe 10. As shown in FIGS. 1 and 2C, a liquid supply tube 15 removably couples liquid source 21, (e.g., a bag of fluid elevated above the surgical site or having a pumping device), with return electrode 55. Preferably, an insulating jacket 14 covers the exposed portions of electrode 55. One of the connector pins 76 is electrically connected to return electrode 55 to couple electrode 55 to power supply 28 via cable 34. A manual control valve 17 may also be provided between the proximal end of return electrode 55 and supply tube 15 to allow the surgical team to regulate the flow of electrically conducting liquid 50.

FIG. 6 illustrates another embodiment of probe 10 where the distal portion of shaft 13 is bent so that electrode terminals extend transversely to the shaft. Preferably, the distal portion of shaft 13 is perpendicular to the rest of the shaft so that electrode array surface 82 is generally parallel to the shaft axis, as shown in FIG. 6. In this embodiment, return electrode 55 is mounted to the outer surface of shaft 13 and is covered with an electrically insulating jacket 18. The electrically conducting fluid 50 flows along flow path 83

through return electrode 55 and exits the distal end of electrode 55 at a point proximal of electrode surface 82. The fluid is directed exterior of shaft to electrode surface 82 to create a return current path from electrode terminals 58, through target tissue 52, to return electrode 55, as shown by current flux lines 60.

FIG. 7 illustrates another embodiment of the invention where electrosurgical system 11 further includes a liquid supply instrument 64 for supplying electrically conducting fluid 50 between electrode terminals 58 and return electrode 55. Liquid supply instrument 64 comprises an inner tubular member or return electrode 55 surrounded by an electrically insulating jacket 18. Return electrode 55 defines an inner passage 83 for flow of fluid 50. As shown in FIG. 7, the distal portion of instrument 64 is preferably bent so that liquid 50 is discharged at an angle with respect to instrument 64. This allows the surgical team to position liquid supply instrument 64 adjacent electrode surface 82 with the proximal portion of supply instrument 64 oriented at a similar angle to probe 10.

FIGS. 8 and 9 illustrate another embodiment of probe 10 where the return electrode is an outer tubular member 56 that circumscribes support member 78 and conductors 42. Insulating jacket 18 surrounds tubular member 56 and is spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 9). Annular gap preferably has a width in the range of 0.15 mm to 4 mm. Ribs 96 can be formed on either the jacket 18 or member 56. The distal end of return electrode 56 is a distance L_1 from electrode support surface 82. Distance L_1 is preferably about 0.5 to 10 mm and more preferably about 1 to 10 mm. The length L_1 of return electrode 56 will generally depend on the electrical conductivity of the irrigant solution.

As shown in FIG. 8, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with the return electrode) and is discharged through the distal end of gap 54. The liquid 50 is then directed around support member 78 to electrode terminals 58 to provide the current pathway between the electrode terminals and return electrode 56. Since return electrode 56 is proximally recessed with respect to electrode surface 82, contact between the return electrode 56 and surrounding tissue is minimized. In addition, the distance L_1 between the active electrode terminals 58 and the return electrode 56 reduces the risk of current shorting therebetween.

The present invention is not limited to an electrode array disposed on a relatively planar surface at the distal tip of probe 10, as described above. Referring to FIGS. 12-14, an alternative probe 10 includes a pair of electrodes 58a, 58b mounted to the distal end of shaft 13. Electrodes 58a, 58b are electrically connected to power supply as described above and preferably have tips 100a, 100b with a screwdriver or flattened shape. The screwdriver shape provides a greater amount of "edges" to electrodes 58a, 58b, to increase the electric field intensity and current density at the edges and thereby improve the cutting ability as well as the ability to limit bleeding from the incised tissue (i.e., hemostasis).

As shown in FIG. 12, current flows between electrode tips 100a and 100b as indicated by current flux lines 60 to heat the target tissue 52. The surgeon then moves probe 10 transversely across tissue 52 to effect an incision 102 in tissue 52, as shown in FIG. 14.

Other modifications and variations can be made to disclose embodiments without departing from the subject invention as defined in the following claims. For example, shaft 13 of probe 10 may have a variety of configurations

other than the generally linear shape shown in FIGS. 1-8. For example, shaft 13 may have a distal portion that is angled, in the range of 10° to 30° (FIG. 10) or 90° (FIGS. 11 and 6), to improve access to the operative site of the tissue 52 being ablated or cut (see FIG. 10). A shaft having a 90° bend angle may be particularly useful for accessing gingiva located in the back portion of the patient's mouth and a shaft having a 10° to 30° bend angle may be useful for accessing gingiva near or in the front of the patient's mouth.

In addition, it should be noted that the invention is not limited to an electrode array comprising a plurality of active electrodes. The invention could utilize a plurality of return electrodes, e.g., in a bipolar array or the like. In addition, depending on other conditions, such as the peak-to-peak voltage, electrode diameter, etc., a single active electrode may be sufficient to develop a vapor layer and induce the discharge of energy to ablate or cut tissue, as described above.

By way of example, FIGS. 21 and 22 illustrate the design of a probe 10 according to the present invention comprising a single active electrode 58 having a tubular geometry. As described above, the return electrode may be an outer tubular member 56 that circumscribes insulated conductor 42 and adhesive bonding material 79 which, in turn, adhesively joins to active electrode support members 48a and 48b. Electrode support members 48a and 48b may be ceramic, glass ceramic or other electrically insulating material which resists carbon or arc tracking. A preferred electrode support member material is alumina. In the example embodiment, a solid rod of alumina forms an inner portion 48b of electrode support member 48 and a hollow tube of alumina forms an outer portion 48a of electrode support member 48. Tubular shaped active electrode 58 may be fabricated using shaped cylinder of this metal comprising an electrically conductive metal, such as platinum, tantalum, tungsten, molybdenum, columbium or alloys thereof. Active electrode 58 is connected to connector 19 (see FIG. 2C) via an insulated lead 108. An electrically insulating jacket 18 surrounds tubular member 56 and may be spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 22). Annular gap 54 preferably has a width in the range of 0.15 to 4 mm. Ribs 96 can be formed on either jacket 18 or tubular member 56. The distal end of the return electrode 56 is a distance L_1 from electrode support surface 82. Distance L_1 is preferably about 0.5 mm to 10 mm and more preferably about 1 to 10 mm. The length L_1 of return electrode 56 will generally depend on the electrical conductivity of the irrigant solution.

As shown in FIG. 21, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with return electrode 56) and is discharged through the distal end of gap 54. The liquid 50 is then directed around electrode support member 48a to electrode terminal 58 to provide the current pathway between electrode terminal 58 and return electrode 56. As described above, the active and return electrodes are connected to voltage supply 28 via cable 34 (see FIG. 1).

FIGS. 23 and 24 illustrate further embodiments of electrosurgical probes according to the present invention. In FIG. 23, a probe 10 comprises a multiplicity of electrodes 58 which converge to a single electrode lead 42. As shown, a central electrode 105 extends to the proximal end of the probe shaft for connection to connector 19 (FIG. 2C). The remainder of the electrodes 58 extend through a portion of the probe shaft and are electrically coupled to central electrode 105 by, for example, a weld, solder joint or crimp connection 100. In FIG. 24, an electrosurgical probe 10

comprises a single electrode 58 connected to a single electrode lead 42. As described above, the active and return electrodes are connected to voltage supply 28 via cable 34 (see FIG. 1).

Both of the single active electrode configurations depicted in FIGS. 21-24 may be used with the integral supply means and return electrodes described above in FIGS. 2-11, 30 and 31. Alternatively, these probe configurations may be operated in body cavities already containing an electrically conducting liquid 50, obviating the need for either an integral supply of said liquid or an electrically insulating sleeve to form a conduit for supply of the electrically conducting liquid 50. Instead, an electrically insulating covering would be applied to substantially all of the return electrode 56 (other than the proximal portion).

FIG. 15 illustrates the current flux lines associated with an electric field 120 applied between the active and return electrodes 56, 58 when a voltage is applied therebetween. As shown, the electric field intensity is substantially higher in the region 88 at the tip of the electrode 58 because the current flux lines are concentrated in these regions. This high electric field intensity leads to induced molecular breakdown of the target tissue through molecular dissociation. Preferably, the electric field intensity is sufficient to ionize the vaporized electrically conducting liquid 50 in a thin layer 124 between the distal tip 122 of the active electrode 58 and the target tissue 52, as shown in FIG. 16. The vapor layer 124 will usually have a thickness of about 0.02 to 2.0 mm.

As shown in FIG. 16, the electric field ionizes the vapor layer due to the presence of an ionizable species (e.g., sodium) within the vapor layer to create a plasma. This ionization, under optimal conditions, induces the discharge of highly energetic electrons and/or photons from the vapor layer. The photon and/or the energetic electrons cause disintegration of the tissue molecules adjacent to the vapor layer. FIG. 16 illustrates the issuance of bubbles 126 of non-condensable gaseous products resulting from the disintegration of tissue at the target site.

The system and method of the present invention is also useful in dermatological procedures, i.e., surface tissue ablation on the patient's outer skin or epidermis. For example, the probe of the present invention can be used for the removal of tissue abnormalities, pigmentations, such as freckles, tattoos, age or liver spots, birth marks, malignant melanomas, and superficial lentigines in the epidermis, and other unwanted tissue, such as soft fatty tissue, cutaneous angiodysplasia, e.g., skin angioloma, malignant tumor tissue, lumbago (i.e., tissue bulges extending from the vertebrae) or the like. In addition, the probe of the present invention may be used for removing surface layers of the epidermis to provide younger looking skin (tissue rejuvenation) or for incising, dividing and resecting tissue during cosmetic surgery procedures.

FIG. 17 illustrates an exemplary embodiment, where an electrosurgical probe 130 is utilized to remove the surface layers of the epidermis 140. Probe 130 includes a shaft 132 coupled to a proximal handle 134 for holding and controlling shaft 132. Similar to previous embodiments, probe 130 includes an active electrode array 136 at the distal tip of shaft 132, an annular return electrode 138 extending through shaft 132 and proximally recessed from the active electrode array 136 and an annular lumen 142 between return electrode 138 and an outer insulating sheath 144. Probe 130 further includes a liquid supply conduit 146 attached to handle 134 and in fluid communication with lumen 142 and a source of electrically conducting fluid (not shown) for

delivering the fluid past return electrode 138 to the target site on the epidermis 140. As discussed above, electrode array 136 is preferably flush with the distal end of shaft 132 or distally extended from the distal end by a small distance (on the order of 0.005 inches) so to minimize the depth of ablation. Preferably, the distal end of shaft 132 is beveled to improve access and control of probe 130 while treating the epidermal tissue.

The voltage will preferably be sufficient to establish high electric field intensities between the active electrode array 136 and the epidermal tissue 140 to thereby induce molecular breakdown or disintegration of several cell layers of the epidermal tissue. As described above, a sufficient voltage will be applied to develop a thin layer of vapor within the electrically conducting fluid and to ionize the vaporized layer or region between the active electrode(s) and the target tissue. Energy in the form of photons and/or energetic electrons are discharged from the vapor layer to ablate the epidermal tissue, thereby minimizing necrosis of surrounding tissue and underlying cell layers, such as cell structures in the stratum lucidum and/or stratum granulosum.

FIGS. 18-20 illustrate an exemplary embodiment of another important application of the present invention. As discussed above, the probe of the present invention may be particularly useful for boring a channel through tissue by axially translating the probe towards the tissue as the tissue is disintegrated by the mechanisms discussed above. In the exemplary embodiment, the probe of the present invention is used in a transmyocardial revascularization procedure to form channels from the myocardium to the ventricular cavity to perfuse the myocardium. This procedure is an alternative to coronary artery bypass surgery for treating coronary artery disease. The channels allow oxygen enriched blood flowing into the ventricular cavity from the aorta to directly flow into the myocardium; rather than exiting the heart and then flowing back into the myocardium through the coronary arteries.

As shown in FIG. 18, electrosurgical probe 10 is positioned into one of the ventricular cavities of the heart, in this case, the right ventricle 200. Electrosurgical probe 10 may be introduced into the right ventricle 200 in a variety of procedures that are well known in the art, such as a thoracotomy, sternotomy or minimally invasive procedures. In the representative embodiment, probe 10 is introduced into the vasculature of the patient through a percutaneous penetration and axially translated via a guide catheter 202 through one of the major vessels to the right ventricular cavity 204. A preferred embodiment incorporates a steerable guide catheter 202 which can be externally controlled by the surgeon to direct the distal portion of the guide catheter 202 and probe 10 to the target site(s) in ventricular cavity 204.

Referring to FIG. 19, ventricle wall 206 comprises an epicardium 208, a myocardium 210 and an endocardium 212. In the representative embodiment, probe 10 will form a channel 214 or artificial vessel from the ventricular cavity 206, through the endocardium 212 and into the myocardium 210 to thereby increase myocardial blood flow from the endocardium 212 to the myocardium 210. The location of channel 214 may be selected based on familiar epicardial anatomic landmarks, such as the epicardial branches of the coronary arteries. Guide catheter 202 is positioned adjacent the inner endocardial wall and probe 10 is axially translated so that the active electrode 58 at its distal end is positioned proximate the heart tissue. In this embodiment, the probe includes a single, annular electrode 58 at its distal tip for ablation of the heart tissue. However, it will be readily recognized that the probe may include an array of electrode terminals as described in detail above.

Electrically conducting liquid 50 is delivered through an annular lumen 220 between an annular return electrode 222 and an insulating sheath 224 of the probe. Return electrode 222 is recessed from the distal end of active electrode 58, preferably about 0.025 to 0.050 inches. Alternatively, the return electrode may be positioned on the exterior surface (skin) of the patient, or it may be located nearby on a more proximal position of the probe. Similar to the above embodiments, a high frequency voltage (e.g., 100 kHz) is applied between active electrode(s) 58 and return electrode 222 to establish a current flow therebetween that ablates or disintegrates the heart tissue. The high frequency voltage will preferably be sufficient to vaporize a thin layer of the electrically conducting liquid and to induce the discharge of photon and/or electron energy from the vapor layer to provide cold ablation of the heart tissue.

Ablation of the tissue may be facilitated by axially reciprocating and/or rotating the probe within guide catheter 202 a distance of between about 0.05 to 0.20 inches. This axial reciprocation or rotation allows the electrically conducting liquid 50 to flow over the tissue surface being canalized, thereby cooling this tissue and preventing significant thermal damage to the surrounding tissue cells.

FIG. 20 illustrates an alternative embodiment of the probe of FIG. 1. In this embodiment, the probe 260 includes a central lumen 262 having a proximal end attached to a suitable vacuum source (not shown) and an open distal end 266 for aspirating the target site. The active electrode is preferably a single annular electrode 268 surrounding the open distal end 266 of central lumen 262. Central lumen 262 is utilized to remove the ablation products (e.g., liquids and gases) generated at the target site and excess electrically conductive irrigant during the procedure.

In both of the above embodiments, the present invention provides localized ablation or disintegration of heart tissue to form a revascularization channel 214 of controlled diameter and depth. Usually, the diameter will be in the range of 0.5 mm to 3 mm. Preferably, the radio frequency voltage will be in the range of 400 to 1400 volts peak-to-peak to provide controlled rates of tissue ablation and hemostasis while minimizing the depth of necrosis of tissue surrounding the desired channel. This voltage will typically be applied continuously throughout the procedure until the desired length of the channel 214 is completely formed. However, the heartbeat may be monitored and the voltage applied in pulses that are suitably timed with the contractions (systole) of the heart.

It should be noted that the above embodiment is merely representative and is not intended to limit the invention. For example, the electrosurgical probe can be used to effect a myocardial revascularization channel from the exterior of the heart into the ventricular cavity. In this procedure, the probe will be introduced into the thoracic cavity and positioned adjacent the epicardial layer of one of the ventricular walls via one of a variety of conventional manners. The above electrosurgical procedure will then be performed as the electrode is translated towards the heart until a channel is formed to the ventricular cavity.

The system and method of the present invention may also be useful to efficaciously ablate (i.e., disintegrate) cancer cells and tissue containing cancer cells, such as cancer on the surface of the epidermis, eye, colon, bladder, cervix, uterus and the like. The present invention's ability to completely disintegrate the target tissue can be advantageous in this application because simply vaporizing cancerous tissue may lead to spreading of viable cancer cells (i.e., seeding) to

other portions of the patient's body or to the surgical team in close proximity to the target tissue. In addition, the cancerous tissue can be removed to a precise depth while minimizing necrosis of the underlying tissue.

What is claimed is:

1. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source; positioning the active electrode in close proximity to the target site in the presence of an electrically conducting terminal; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

2. The method of claim 1 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

3. The method of claim 2 wherein the isolated electrode terminals each have a contact surface area in the range of about 0.25 mm² to 50.0 mm².

4. The method of claim 2 wherein the isolated electrode terminals have circular contact surfaces with an area in the range from 0.01 mm² to 1 mm².

5. The method of claim 2 wherein the electrode terminals are spaced from each other a distance of about 0.0005 to 2.0 mm.

6. The method of claim 2 wherein the electrode array is disposed over a distal tip of an electrosurgical probe.

7. The method of claim 2 wherein the electrode terminals comprises a material with a relatively low thermal conductivity.

8. The method of claim 7 wherein the electrode materials comprises a material selected from the group consisting of titanium, tungsten, platinum, aluminum and tantalum.

9. The method of claim 2 wherein the return electrode has a distal end positioned proximal to the electrode array.

10. The method of claim 2 wherein the electrode height of the most distal portion of any of the electrode terminals relative to the most proximal portion of said electrode terminals exposed to the electrically conducting fluid is in the range from 0.0 to 2.0 mm.

11. The method of claim 2 wherein the electrode terminals are surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate proximal portions of the electrode terminals from the electrically conductive fluid, the insulating matrix comprising an inorganic material.

12. The method of claim 11 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

13. The method of claim 1 wherein at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.

14. The method of claim 1 wherein at least a portion of the energy is in the form of energetic electrons.

15. The method of claim 14 wherein the energy of the energetic electrons is sufficient to cause disassociation or disintegration of molecules of the body structure.

16. The method of claim 14 wherein the energy evolved by the energetic electrons is greater than 3 eV.

17. The method of claim 1 wherein the high frequency voltage is at least 200 volts peak to peak.

18. The method of claim 1 wherein the voltage is in the range from 500 to 1400 volts peak to peak.

19. The method of claim 1 wherein the electrode terminal is positioned between 0.02 to 5 mm from the target site.

20. The method of claim 1 wherein the vapor layer has a thickness of about 0.02 to 2.0 mm.

21. The method of claim 1 wherein the distance between the most proximal portion of the electrode terminal and the most distal portion of the return electrode is in the range from 0.5 to 10 mm.

22. The method of claim 1 wherein the electrode terminal and the return electrode are of comparable size and comprise a bipolar array of isolated electrode terminals which both come in close proximity or in contact with the body structure.

23. The method of claim 1 wherein the liquid phase of the electrically conducting fluid has a conductivity greater than 2 mS/cm.

24. The method of claim 1 wherein the liquid phase of the electrically conductive fluid comprises isotonic saline.

25. The method of claim 1 wherein the electrode height of the most distal portion of the electrode terminal relative to the most proximal portion of the electrode terminal exposed to the electrically conducting fluid is in the range from 0.0 to 2.0 mm.

26. A method for applying energy to a target site on a patient body structure comprising:

providing an active electrode and a return electrode electrically coupled to a high frequency voltage source; positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being in the range from 500 to 1400 volts peak to peak.

27. The method of claim 26 wherein the high frequency voltage is in the range from 700 to 900 volts peak to peak.

28. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source; positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to impart sufficient energy into the target site to ablate the body structure without causing substantial tissue necrosis below the surface of the body structure underlying the ablated body structure.

29. The method of claim 28 wherein the applying step comprises:

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal; and inducing the discharge of photons to the target site in contact with the vapor layer.

30. The method of claim 28 wherein the applying step comprises:

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the active electrode surface; and

inducing the discharge of energetic electrons to the target site in contact with the vapor layer.

31. The method of claim 28 wherein the depth of necrosis is 0 to 400 microns.

32. A method for applying energy to a target site on a patient body structure comprising:

providing an active electrode electrically coupled to a high frequency voltage source;

positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

generating a voltage gradient between the electrode terminal and tissue at the target site, the voltage gradient being sufficient to create an electric field that cause the breakdown of tissue through molecular dissociation or disintegration.

33. The method of claim 32 wherein the generating step comprises:

providing a return electrode electrically coupled to a high frequency voltage source;

applying a high frequency voltage between the electrode terminal and the return electrode; and

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal.

34. The method of claim 33 further comprising developing a film layer of vapor between the active electrode and the body structure at the target site.

35. The method of claim 33 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.

36. The method of claim 35 wherein the cooling step includes translating the distal surface of the electrode terminal over the target site to allow the electrically conducting fluid to contact the tissue after the tissue has been subjected to the electric field.

37. The method of claims 1 and 28 wherein the electrode terminal is surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate the proximal portion of the electrode terminal from the electrically conductive fluid, the insulating matrix comprising an inorganic material.

38. The method of claim 37 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

39. The method of claim 37 wherein the distal surface of the electrode terminal is recessed below the surface of the insulating matrix by a distance from 0.01 mm to 1.0 mm.

40. The method of claim 37 wherein the distal surface of the electrode terminal is flush with the surface of the insulating matrix.

41. The method of claims 28 and 32 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

42. The method of claim 41 wherein the generating step comprises:

providing a return electrode electrically coupled to a higher frequency voltage source;

applying a high frequency voltage between the return electrode and the array of electrode terminals; and

vaporizing the electrically conducting fluid in a thin layer over one or more of the electrode terminals of the array.

43. The method of claim 42 further comprising developing a film layer of vapor between one or more of the electrode terminals and the target site.

44. The method of claim 42 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.

45. The method of claims 1 and 33 wherein the density of the vapor layer is less than about 10^{20} atoms/cm³.

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46. The method of claims 1 and 34 wherein the electrode terminal is configured to promote bubble nucleation causing the formation of the vapor layer.

47. The method of claims 1 and 28 wherein the electrode terminal has a contact surface area in the range of about 0.25 mm² to 50 mm².

48. The method of claims 26 and 28 wherein the high frequency voltage is at least 200 volts peak to peak.

49. The method of claims 26 and 28 wherein the high frequency voltage is in the range from about 500 to 1400 volts peak to peak.

50. The method of claims 26 and 28 wherein the electrode terminal is positioned between 0.02 to 2.0 mm from the target site.

51. The method of claims 26 and 28 wherein the electrode terminal and the return electrodes comprise a bipolar array of isolated electrode terminals.

52. The method of claims 1 and 28 further comprising cooling the tissue with the electrically conducting fluid to

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reduce the temperature rise of those portions of the body structure adjacent the target site.

53. The method of claim 52 wherein the cooling step includes translating the distal surface of the active electrode over the target site to allow the electrically conducting fluid to contact the tissue after the tissue has been subjected to the electric field.

54. The method of claims 1 and 28 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.

55. The method of claims 1 and 28 wherein the target site is a tumor within or on the patient's body.

56. The method of claims 26 and 28 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,697,882
DATED : December 16, 1997
INVENTOR(S) : Philip E. Eggers, et. al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

IN THE CLAIMS:

23. A method for applying energy to a target site on a patient body structure comprising:
providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;
positioning the [active] electrode terminal in close proximity to the target site in the presence of an electrically conducting [terminal] fluid; and
applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

Signed and Sealed this
Seventh Day of April, 1998



Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT : 5,697,882
DATED : December 16, 1997
INVENTOR(S) : Philip E. Eggers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 24, lines 6-18, claim 1, should read as follows:

1. A method for applying energy to a target site on a patient body structure comprising:
- providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;
 - positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and
 - applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

This certificate supersedes Certificate of Correction issued April 7, 1998.

Signed and Sealed this
Twenty-fifth Day of August, 1998

Attest:



Attesting Officer

BRUCE LEHMAN

Commissioner of Patents and Trademarks

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,697,882

Page 1 of 2

DATED : December 16, 1997

INVENTOR(S) : Philip E. Eggers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

IN THE CLAIMS:

37. The method of claims 23 or 48 wherein the electrode terminal is surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate the proximal portion of the electrode terminal from the electrically conductive fluid, the insulating matrix comprising an inorganic material.

45. The method of claims 23 or 55 wherein the density of the vapor layer is less than about 10^{20} atoms/cm³.

46. The method of claims 23 or 50 wherein the electrode terminal is configured to promote bubble nucleation causing the formation of the vapor layer.

47. The method of claims 23 or 48 wherein the electrode terminal has a contact surface area in the range of about 0.25 mm² to 50 mm².

48. The method of claims 48 or 52 wherein the high frequency voltage is at least 200 volts peak to peak.

49. The method of claims 48 or 52 wherein the high frequency voltage is in the range from about 500 to 1400 volts peak to peak.

50. The method of claims 48 or 52 wherein the electrode terminal is positioned between 0.02 to 2.0 mm from the target site.

51. The method of claims 48 or 52 wherein the electrode terminal and the return electrodes comprise a bipolar array of isolated electrode terminals.

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,697,882

Page 2 of 2

DATED : December 16, 1997

INVENTOR(S) : Philip E. Eggers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

52. The method of claims 23 or 48 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.

54. The method of claims 23 or 48 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.

55. The method of claims 23 or 48 wherein the target site is a tumor within or on the patient's body.

56. The method of claims 48 or 52 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

Signed and Sealed this

Second Day of May, 2000

Attest:



Q. TODD DICKINSON

Attesting Officer

Director of Patents and Trademarks

CERTIFICATE OF SERVICE

I hereby certify that on October 1, 2004, I caused two copies of the foregoing Corrected Non-Confidential Brief For Defendant/Counterclaimant-Appellant, Smith & Nephew, Inc. to be served as follows:

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A handwritten signature in cursive script, reading "Judith Best", followed by a horizontal line.

CERTIFICATE OF COMPLIANCE

Counsel for Defendant/Counterclaimant-Appellant, Smith & Nephew, Inc., certifies that the foregoing brief complies with the type-volume limitations of the Federal Rules of Appellate Procedure 32(a)(7)(B). According to the word count of the word-processing system used to prepare this brief, there are 13,711 words in this brief pursuant to the Court's rules of counting.



Ruffin B. Cordell

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